RULE16

# U.S. District Court District of New Jersey [LIVE] (Newark) CIVIL DOCKET FOR CASE #: 2:15-cv-03690-ES-MAH

CHANN et al v. PREMIER ORTHOPAEDIC ASSOCIATES SURGICAL CENTER, LLC et al

Assigned to: Judge Esther Salas

Referred to: Magistrate Judge Michael A. Hammer

Case in other court: Superior Court, Law Division: Essex

County, ESX-L-07568-14

Cause: 28:1441 Notice of Removal- Product Liability

Date Filed: 06/02/2015 Jury Demand: Plaintiff

Nature of Suit: 367 Personal Injury: Health Care/Pharmaceutical Personal

Injury Product Liability

Jurisdiction: Federal Question

**Plaintiff** 

KENNETH CHANN, SR.

represented by JEFFREY MARK KEISER

76 EUCLID AVENUE SECOND FLOOR

HADDONFIELD, NJ 08033

(856) 354-6266 *LEAD ATTORNEY* 

ATTORNEY TO BE NOTICED

**Plaintiff** 

LAURA CHANN

represented by JEFFREY MARK KEISER

(See above for address)

LEAD ATTORNEY

ATTORNEY TO BE NOTICED

**Plaintiff** 

EMIKO KANESHIKI

represented by JEFFREY MARK KEISER

(See above for address) *LEAD ATTORNEY* 

ATTORNEY TO BE NOTICED

Plaintiff

JOSEPH LANGLEY

represented by JEFFREY MARK KEISER

(See above for address) *LEAD ATTORNEY* 

ATTORNEY TO BE NOTICED

**Plaintiff** 

SAMUEL ELWELL

represented by JEFFREY MARK KEISER

(See above for address) *LEAD ATTORNEY* 

ATTORNEY TO BE NOTICED

Case 1:13-md-02419-RWZ Document 2414-1 Filed 11/13/15 Page 2 of 154

CM/ECF LIVE - U.S. District Court for the District of New Jersey

Page 2 of 5

**Plaintiff** 

HELEN ELWELL represented by JEFFREY MARK KEISER

(See above for address) *LEAD ATTORNEY* 

ATTORNEY TO BE NOTICED

**Plaintiff** 

EDWARD HIRALDO represented by JEFFREY MARK KEISER

(See above for address)

LEAD ATTORNEY

ATTORNEY TO BE NOTICED

**Plaintiff** 

MARILYN HIRALDO represented by JEFFREY MARK KEISER

formerly known as(See above for address)MARILYN MASONETLEAD ATTORNEY

ATTORNEY TO BE NOTICED

**Plaintiff** 

ELDEAN LANGLEY represented by JEFFREY MARK KEISER

(See above for address)

LEAD ATTORNEY

ATTORNEY TO BE NOTICED

V.

**Defendant** 

PREMIER ORTHOPAEDIC represented by CHRISTOPHER M. WOLK

ASSOCIATES SURGICAL

CENTER, LLC

BLUMBERG & WOLK, LLC

158 DELAWARE STREET

PO BOX 68

WOODBURY, NJ 08906

Email:

cwolk@blumberglawoffices.com

LEAD ATTORNEY

ATTORNEY TO BE NOTICED

Defendant

PREMIER ORTHOPAEDIC AND represented by CHRISTOPHER M. WOLK SPORTS MEDICINE ASSOCIATES (See above for address)

OF SOUTH JERSEY, LLC

LEAD ATTORNEY

doing business as ATTORNEY TO BE NOTICED PREMIER ORTHOPAEDIC AND

Defendant

SPORTS MEDICINE ASSOCIATES

represented by

KIMBERLEY YVETTE SMITH,

M.D.

also known as

KIMBERLEY YVETTE SMITH-

MARTIN, M.D.

**Defendant** 

JOHN B. CATALANO, M.D.

Defendant

THOMAS A. DWYER, M.D.

CHRISTOPHER M. WOLK

(See above for address) LEAD ATTORNEY

ATTORNEY TO BE NOTICED

represented by CHRISTOPHER M. WOLK

(See above for address) LEAD ATTORNEY

ATTORNEY TO BE NOTICED

Defendant

NITESH BHAGAT, M.D.

**Defendant** 

BARRY J. CADDEN

Defendant

GREGORY CONIGLIARO

Defendant

LISA CONIGLIARO CADDEN

Defendant

DOUGLAS CONIGLIARO

Defendant

CARLA CONIGLIARO

**Defendant** 

GLENN A. CHIN

Defendant

AMERIDOSE, LLC

Defendant

**GDC PROPERTIES** 

MANAGEMENT, LLC

Defendant

**MEDICAL SALES** 

MANAGEMENT, INC.

Defendant

# MEDICAL SALES MANAGEMENT SW. INC.

#### **Defendant**

ARL BIO PHARMA, INC.

doing business as ANALYTICAL RESEARCH **LABORATORIES** 

## **Defendant**

LIBERTY INDUSTRIES, INC.

#### **Defendant**

#### UNIFIRST CORPORATION

doing business as UNICLEAN CLEANROOM **SERVICES** 

#### **Defendant**

#### **JOHN DOES (1-10)**

ficititious unknown individuals

# **Defendant**

# JOHN DOE(S) CORPORATIONS

(1-100)

fictitious unknown corporations

# **Defendant**

# **JOHN DOE(S) BUSINESS**

**ENTITIES (1-100)** 

fictitious unknown non corporation business entities

#### Defendant

## **JOHN DOE(S), M.D. (1-100)**

fictitious unknown medical doctors

Date Filed	#	Docket Text
06/02/2015	1	NOTICE OF REMOVAL by KIMBERLEY YVETTE SMITH, MD, PREMIER ORTHOPAEDIC AND SPORTS MEDICINE ASSOCIATES OF SOUTH JERSEY, LLC, THOMAS A. DWYER, MD, PREMIER ORTHOPAEDIC ASSOCIATES SURGICAL CENTER, LLC from Superior Court Law Division Essex, case number ESX-L-7568-14. (Filing and Admin fee \$ 400 receipt number 0312-6426501), filed by KIMBERLEY YVETTE SMITH, MD, PREMIER ORTHOPAEDIC AND SPORTS MEDICINE ASSOCIATES OF SOUTH JERSEY, LLC, THOMAS A. DWYER, MD, PREMIER

	**:00:00*******************************	ORTHOPAEDIC ASSOCIATES SURGICAL CENTER, LLC. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D)(in-tk, ) Modified on 6/5/2015 (jr). (Entered: 06/03/2015)	Management
10/02/2015	2	LETTER ORDER: Initial Scheduling Conference set for 10/26/2015 at 11:00 a.m. in Newark - Courtroom 2C before Magistrate Judge Michael A. Hammer. So Ordered by Magistrate Judge Michael A. Hammer on 10/2/2015. (jqb, ) (Entered: 10/02/2015)	
10/07/2015	3	Letter from To Judge Salas advising of the filing of a Notice of Potential Tag- Along in the District of Massachusetts to initiate transfer of case. (BLUMBERG, JAY) (Entered: 10/07/2015)	
10/23/2015		Remark: Parties must electronically file a joint discovery plan by 9:00 a.m. on 10/26/2015. (jqb, ) (Entered: 10/23/2015)	
10/23/2015	4	Letter from Jeffrey M. Keiser, Esq. (jqb, ) (Entered: 10/23/2015)	1
10/23/2015	5	TEXT ORDER: The Initial Scheduling Conference set for 10/26/2015 is adjourned without a new date. So Ordered by Magistrate Judge Michael A. Hammer on 10/23/2015. (jqb, ) (Entered: 10/23/2015)	t NO bocuments attached
10/27/2015	6	TEXT ORDER: On or before November 13, 2015, the parties will advise the Court of the status of their application to consolidate this matter with MDL No. 13-2419-RWZ pending in the District of Massachusetts. So Ordered by Magistrate Judge Michael A. Hammer on 10/27/2015. (MAH) (Entered: 10/27/2015)	5 NO ents Souments affoched

#### Case 1:13-md-02419-RWZ Document 2414-1 Filed 11/13/15 Page 6 of 154

JAY J. BLUMBERG \*

jjblumberg@blumberglawoffices.com
CERTIFIED CIVIL TRIAL ATTORNEY
CHRISTOPHER M. WOLK \*
cwolk@blumberglawoffices.com

KIRA FEENY SPAMAN\*
kspaman@blumberglawoffices.com

JEFFREY P. CATALANO+ jcatalano@biumberglawoffices.com

OF COUNSEL
JEAN S. CHETNEY\*
jchetney@blumberglawoffices.com

\*MEMBERS OF P.A and N.J. BAR +MEMBERS OF N.Y. and NJ BAR



June 1, 2015

#### **VIA ECF**

Martin Luther King Building & U.S. Courthouse 50 Walnut Street Newark, NJ 07101

Re: Chann, et al. v. Premier Orthopaedic Associates Surgical Center

#### Dear Sir/Madam:

Attached please find the notice of removal and consent for removal with regard to the above referenced case. The plaintiff did consent to having this matter removed to Federal Court so it could eventually be incorporated into the currently pending Multidistrict Litigation. Unfortunately the notice of removal and consent order is being filed after the case has been administratively dismissed due to lack of prosecution. This is through no fault of the plaintiff and the defendants agree and consent that the matter should be placed again on the active docket so it can be removed to Federal Court in accordance with the attached.

Please contact my office if there should be any question or concern about this.

Cordially,

BLUMBERG & WOLK, LLC

Christopher M. Wolk

CMW/dm

Encl.

C: Jeff Keiser, Esq. (w/encl.)
Mark Zamora, Esq. (w/encl.)
Fredrick Fern, Esq. (w/encl.)
Matthew Moriarty, Esq. (w/encl.)
James Rehnquist, Esq. (w/encl.)
Joseph Lang, Esq. (w/encl.)
Peter G. Hermes, Esq. (w/encl.)

#### 

Blumberg & Wolk, LLC 158 Delaware Street P.O. Box 68 Woodbury, NJ 08096 (856) 848-7472

Counsel for Defendants Premier Orthopaedic and Sports Medicine Associates of Southern New Jersey, LLC, trading as Premier Orthopaedic Associates, Premier Orthopaedic Associates Surgical Center, LLC, Kimberly Yvette Smith, M.D., a/k/a Kimberly Yvette Smith-Martin, M.D., Thomas Dwyer, M.D., Richard C. DiVerniero, M.D., and Richard Strauss, M.D.

# UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

KENNETH CHANN, SR., LAURA CHANN, EMIKO KANESHIKI, JOSEPH LANGLEY, ELDEAN LANGLEY, SAMUEL ELWELL, HELEN ELWELL, EDWARD HIRALDO and MARILYN HIRALDO (MASONET)

Plaintiffs,

V.

PREMIER ORTHOPAEDIC ASSOCIATES SURGICAL CENTER, PREMIER ORTHOPAEDIC SPORTS et al.

Defendants.

Civil Action No.:	A -y
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NOTICE OF REMOVAL

PLEASE TAKE NOTICE that, pursuant to 28 U.S.C. §§ 157, 1334(b), 1441(a) and 1452(a), Defendants Premier Orthopaedic and Sports Medicine Associates of Southern New Jersey, LLC, trading as Premier Orthopaedic Associates, Premier Orthopaedic Associates Surgical Center, LLC, Kimberly Yvette Smith, M.D., a/k/a Kimberly Yvette Smith-Martin, M.D., Thomas

Dwyer, M.D., Richard C. DiVerniero, M.D., and Richard Strauss, M.D. ("Removing Defendants") hereby remove the above-entitled action to this Court based upon the supporting grounds set forth below. Removing Defendants, appearing solely for the purpose of this Removal and for no other purpose, and preserving all defenses available to them, state as follows:

- 1. On or about December 9, 2014, an action was commenced in the Superior Court of New Jersey, Law Division, Essex County, captioned Kenneth Chann Sr., Laura Chann, Emiko Kaneshiki, Joseph Langley, Eldean Langley, Samuel Elwell, Helen Elwell, Edward Hiraldo, and Marilyn Hiraldo (Masonet), Plaintiffs v. Premier Orthopaedic Associates Surgical Center, LLC; Premier Orthopaedic and Sports Medicine Associates of South Jersey, LLC, d/b/a Premier Orthopaedic and Sports Medicine Associates; Kimberly Yvette Smith, M.D. (a/k/a Kimberly Yvette Smith-Martin, M.D.); John B. Catalano, M.D.; Thomas A. Dwyer, M.D., Nitesh Bhagat, M.D., Barry J. Cadden; Gregory Conigliarol Lisa Conigliaro Cadden; Douglas Conigliaro; Carla Conigliaro; Glenn A. Chinn; Ameridose, LLC; GDC Properties Management, LLC; Medical Sales Management, Inc.: Medical Sales Management SW, Inc.; ARL Bio Pharma, Inc. D/B/A Analytical Research Laboratories, Liberty Industries, Inc.; UniFirst Corporation (d/b/a "Uniclean Cleanroom Services"); John Does (1-10) fictitious unknown individuals; John Doe(s) Corporations (1-100) fictitious unknown corporations; JOHN DOE(S) Business Entities (1-100), fictitious unknown non corporation business entities; and John Doe(s), M.D. (1-100) fictitious unknown medical doctors, Defendants, Docket No. ESX-L-7568-14.
- 2. A copy of the Complaint and copies of all other process, pleadings, and orders received by the Removing Defendants are collectively attached as Exhibit A.

- Removal is made with the consent of all parties, pursuant to the Plaintiffs' Consent to Removal attached as <u>Exhibit B</u>.
- 4. On December 21, 2012, New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC") filed a voluntary petition seeking relief under Chapter 11 of Title 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Massachusetts (the "Bankruptcy Proceeding"), and thus automatically staying all actions against NECC.
- 5. On February 12, 2013, the Judicial Panel on Multidistrict Litigation ("Panel") issued an order establishing MDL No. 2419 *In re New England Compounding Pharmacy, Inc. Products Liability Litigation* in the United States District Court for the District of Massachusetts before the Honorable F. Dennis Saylor IV (the "MDL Transfer Order") (attached as <a href="Exhibit C">Exhibit C</a>). The MDL Transfer Order centralized the cases "relating to injuries arising from the alleged contamination of the injectable steroid methylprednisolone acetate at the New England Compounding Pharmacy facility in Framingham, Massachusetts" in the District of Massachusetts. (Exhibit C at 1.)
- Thereafter, on March 10, 2013, Paul D. Moore, the Chapter 11 Trustee, moved for an
  order of the District Court for the District of Massachusetts to transfer to itself all related
  personal injury and wrongful death actions pursuant to 28 U.S.C. § 157.
- 7. On May 31, 2013, Judge Saylor partially granted the motion, transferring all pending and future cases, filed in state or federal court, against NECC or an affiliate, to the District of Massachusetts (attached as <u>Exhibit D</u>). Chann et al. v. Premier Orthopaedic Associates, et al. names various NECC affiliates as co-defendants to instant Removing Defendants.

- 8. On February 11, 2014, MDL No. 2419 was reassigned from the Honorable F. Dennis Saylor IV to the Honorable Rya W. Zobel.
- 9. In the Complaint, Plaintiffs allege to have sustained damages as a result of personal injuries caused by exposure to methylprednisolone acetate compounded by NECC.
- 10. Section 1334 of Title 28 of the United States Code provides that district courts have jurisdiction over "all civil proceedings arising under Title 11, or arising in or *related to* cases under Title 11." 28 U.S.C. § 1334(b) (emphasis added). "A party may remove any claim or cause of action in a civil action ... to the district court for the district where such civil action is pending, if such district court has jurisdiction of such claim or cause of action under section 1334 of this title." 28 U.S.C. § 1452(a).
- Accordingly, removal is proper as Removing Defendants are party to this action under 28
   U.S.C. § 1452(a).
- 12. Accordingly, the district court has "related to" jurisdiction over the claims against Defendants pursuant to 28 U.S.C. §§ 1334(b).
- 13. Further, this action involves common questions of fact with other civil actions currently pending in, or being transferred to, MDL No. 2419. This action will therefore be transferred to the United States District Court for the District of Massachusetts for coordinated pretrial proceedings pursuant to the MDL Transfer Order and 28 U.S.C. §§ 1407.
- 14. Upon removal of this case to this Court, Removing Defendants will file a Notice of Tag Along with the Panel, initiating the process for transfer to MDL No. 2419 currently pending in the United States District Court for the District of Massachusetts before Judge Zobel.

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15. In accordance with 28 U.S.C. § 1446(d), written notice of this Removal will be given to Plaintiffs and filed with the Clerk of the Court for the Superior Court of New Jersey, Law Division, Essex County, promptly following the filing of this Notice.

WHEREFORE, Removing Defendants respectfully remove the action now pending against them in the Superior Court of New Jersey, Law Division, Essex County, to the United States District Court for the District of New Jersey.

Dated: May 29, 2015

Blumberg & Wolk, J

Bv:

7s/ Christopher M. Wolk, Esq.

158 Delaware Street P.O. Box 68 Woodbury, NJ 08096

(856) 848-7472

Counsel for Defendants Premier Orthopaedic and Sports Medicine Associates of Southern New Jersey, LLC, trading as Premier Orthopaedic Associates, Premier Orthopaedic Associates Surgical Center, LLC, Kimberly Yvette Smith, M.D., a/k/a Kimberly Yvette Smith-Martin, M.D., Thomas Dwyer, M.D., Richard C. DiVerniero, M.D., and Richard Strauss, M.D. 

#### **CERTIFICATE OF SERVICE**

I hereby certify that a copy of the foregoing Notice of Removal was served via U.S. Regular mail on this 29<sup>th</sup> day of May, 2015, to the following:

Jeff Keiser, Esq. 76 E. Euclid Ave. Suite 201 Haddonfield, NJ 08033

Mark Zamora, Esq. P.O. Box 660216 Atlanta, GA 30366

Fredrick Fern, Esq. Harris Beach PLLC 100 Wall Street 23<sup>rd</sup> Floor New York, NY 10005

Matthew P. Moriarty, Esq. Tucker Ellis, LLP 925 Euclid Ave., Quite 1150 Cleveland, OH 44115-1414 James Rehnquist, Esq. Goodwin Procter, LLP Exchange Place 53 State Street Boston, MA 02109

Joseph Lang, Esq. Lenox Law Firm 136 Franklin Road Unit B2 Lawrenceville, NJ 08648

Peter G. Hermes, Esq. Hermes, Netburn, O'Connor & Spearing 265 Franklin Street 7<sup>th</sup> Floor Boston MA, 02110

/s/ Christopher M. Wolk, Esq.

# **EXHIBIT A**

# Case 1:13-md-02419-RWZ Document 2414-1 Filed 11/13/15 Page 14 of 154

# SUMMONS

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Attorncy(s)	Jeffrey M. Keiser,	Esquire		~ .	<b></b>
Office Address	76 B. Euclid Ave.,	Suite 201			or Court of
				Nev	v Jersey
Town, State, Z.	ip Code Haddonfiel nber (856) 354-			Essex	
Attorney(s) for		<del></del>	<u> </u>	LAW	COUNTY DIVISION
			·A		······································
NOW WELL CITY	NN, SR., LAURA C	LANN, et at	· 	Docket No: E	SX-L-7568-14
Distratif	YZY_\				•
Plaintif	1(8)			CIVIII	A COUNTY OF THE
Vs.	•				ACTION
PREMIER ORTH	OPAEDIC ASSOCL	ATES SURGICAL		SUN	<b>IMONS</b>
	IER ORTHOPAEDIO	C SPORTS et al			
Defend	ant(s)				
From The State o	f New Jersey To The	Defendant(s) Name	d Above:		
written answer or 35 days from the each deputy clerk online at <a href="http://www.you.must.file.you.">http://www.you.must.file.you.</a> Completed Case In answer or motion and address appea must file and serve want the court to h	motion and proof of date you received this of the Superior Court www.judiciary.state.nj. r written answer or mox 971, Trenton, NJ-(aformation Statement when it is filed. You r above, or to plaintiff a written answer or near your defense.	service with the deps summons, not count is available in the us/pro se/10153 depotion and proof of s 08625-0971. A filing (available from the must also send a coff, if no attorney is a motion (with fee of	outy clerk of the Stating the date you Civil Division Motyclerklawref.pd ervice with the Cogfee payable to deputy clerk of the py of your answering amed above. A te \$175.00 and con	Superior Court in the received it. (A disanagement Office in f.) If the complaint the Treasurer, State the Superior Court) or or motion to plan elephone call will nepleted Case Inform	your attorney must file a e county listed above within rectory of the addresses of a the county listed above and t is one in foreclosure, then a Court, Hughes Justice of New Jersey and a must accompany your ntiff's attorney whose name of protect your rights; you nation Statement) if you
the relief plaintiff	file and serve a writte demands, plus interes property to pay all or	st and costs of suit.	If judgment is en	he court may enter tered against you, f	a judgment against you for he Sheriff may seize your
Services of New Je not eligible for free Services. A direct in the Civil Division	ersey Statewide Hotli e legal assistance, you	ne at 1-888-LSNJ-L I may obtain a refer mation for local Le e in the county liste	AW (1-888-576- ral to an attorney gal Services Offic d above and onlin	5529). If you do no by calling one of th ces and Lawyer Ret	ferral Services is available
TO A (THEY)	2/00/0014				
DATED: 12	2/09/2014				
Name of Defenda	nt to Be Served:	Kimberly Yvette	Smith, M.D.		
Address of Defen	dant to Be Served:	298 S. Delsea Dr	, Vineland, NJ		

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Case 2:15-cv-03690-ES-MAH Document 1-1 Filed 06/02/15 Page 3 of 92 PageID: 150

Law Offices

# JEFFREY M. KEISER, ESQUIRE

Jessey M. Kelser
Certified by the Supreme Court
of New Jersey as Civil Trial Attorney
Lynn A. Godtfring, RN, JD\*
\*NJ and PA Bar

76 E. Euclid Ayenuc Suite 201 Haddonfield, NJ 08033 (856) 354-6266 Fax (856) 354-2322 www.jeffreykelserlawoffice.com

December 9, 2014

Premier Orthopaedic & Sports Medicine Associates 298 S. Delsea Drive Vineland, NJ 08360

Re:

Chann et al v. Premier Orthopaedic Associates, et al Docket No. ESX-L-7568-14

Dear Sir/Madam:

We herewith serve upon you Summons and Complaint in connection with the above captioned matter,

Kindly forward to your attorney or carrier in order that an Answer be entered in your behalf.

Thank you for your attention to this matter.

Yerx truly yours,

JEFFREY M. KEISER

JMK/ki

# Case 1:13-md-02419-RWZ Document 2414-1 Filed 11/13/15 Page 16 of 154

Case 2:15-cv-03690-ES-MAH Document 1-1 Filed 06/02/15 Page 4 of 92 PageID: 151

	SUMMO	ns			
Attorney(s) Office Address	Jeffrey M. Keiser, Esquire 76 E: Euclid Ave., Suite 201	-	rior Court of ew Jersey		
Telephone Num	p Code Haddonfield, NJ 08033	Essex	CVN INVITA		
Attorney(s) for		LAW	COUNTY DIVISION		
		. IJA W	DIVISION		
KENNETH CHAI	NN, SR., LAURA CHANN, et al	Docket No:	ESX-L-7568-14		
Plaintif	f(s)				
Vs.	OPAEDIC ASSOCIATES SURGICAL		CIVIL ACTION SUMMONS		
CENTER, PRÉMI	ER ORTHOPAEDIC SPORTS et al	•			
Defenda		,			
	( )				
attached to this si written answer or 35 days from the each deputy clerk online at http://wyou must file you Complex, P.O. B. completed Case I answer or motion and address appermust file and serv want the court to	named above, has filed a lawsuit against you in immons states the basis for this lawsuit. If you do motion and proof of service with the deputy cle date you received this summons, not counting the of the Superior Court is available in the Civil Daww.judiciary.state.nj.us/pro.se/10153_deptycler! rewritten answer or motion and proof of service ox 971, Trenton, NJ 08625-0971. A filing fee penformation Statement (available from the deputy when it is filed. You must also send a copy of your above, or to plaintiff, if no attorney is named a see a written answer or motion (with fee of \$175.0) thear your defense.	lispute this complaint, york of the Superior Court is edate you received it. (/ivision Management Officamer, pdf.) If the compwith the Clerk of the Supayable to the Treasurer, for clerk of the Superior Co our answer or motion to bove. A telephone call will and completed Case In	n or your attorney must file a in the county listed above within A directory of the addresses of fice in the county listed above at laint is one in foreclosure, then erior Court, Hughes Justice state of New Jersey and a part) must accompany your plaintiff's attorney whose name ill not protect your rights; you formation Statement) if you		
the relief plaintiff	file and serve a written answer or motion within demands, plus interest and costs of suit. If judg property to pay all or part of the judgment.				
services of New not eligible for fre Services. A direction the Civil Division	afford an attorney, you may call the Legal Serv fersey Statewide Hotline at 1-888-LSNJ-LAW (see legal assistance, you may obtain a referral to a tory with contact information for local Legal Se fon Management Office in the county listed abovery state.ni.us/prose/10153_deptyclerklawref.pd	I-888-576-5529). If you in attorney by calling one rvices Offices and Lawye ic and online at f.	do not have an attorney and are of the Lawyer Referral or Referral Services is available		
	-/ ci	uchelle M. erk of the Superior Cou	Amerik 1rt		
DATED:	12/09/2014	•			

Premier Orthopaedic & Sports Medicine Assoc

298 S. Delsea Dr., Vineland, NJ

Revised 11/17/2014, CN 10792-English (Appendix XII-A)

Name of Defendant to Be Served:

Address of Defendant to Be Served:

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Case 2:15-cv-03690-ES-MAH Document 1-1 Filed 06/02/15 Page 5 of 92 PageID: 152

DAIE: OCTOBER 24, 2014
RE: CHANN SR VS PREMIER ORTHOPABDIC ASSOCIATES SURGICA
DOCKET: SSX L -007568 14 IF YOU BELLEVE THAT THE TRACK IS INAPPROPRIATE YOU MUST FILE A CERTIFICATION OF GOOD CAUSE WITHIN 30 DAYS OF THE FILING OF YOUR PLEADING.

PLAINTIFF MUST SERVE COPIES OF THIS FORM ON ALL OTHER PARTIES IN ACCORDANCE MITH R.4:5A-2. OCT 2 9 DISCOVERY IS 450 DAYS AND RUNS FROM THE FIRST ANSWER OR 90 DAYS SERVICE ON THE FIRST DEPENDANT, WHICHEVER COMES FIRST. MJ 08033 TRACK ASSIGNMENT NOTICE JEFFRY M. KEISER
76 EUCLID AVENUE
SECOND FLOCK
HADDONFIELD M. HON GARRY J. FURNARI TRACK 3. IF YOU HAVE ANY QUESTIONS, CONTACT TERM (973) 693-6441 BXT 6411. THE ABOVE CASE HAS BEEN ASSIGNED TO: ATTENTION: THE PRETRIAL JUDGE ASSIGNED IS: COURT TELEPHONE NO. (973) 693-5529 COURT HOURS 8:30 AM - 4:30 PM ESSEX COUNTY - CIVIL DIVISION SUPERIOR COURT OF NJ 465 MARTIN LUTHER KING JR BLVD NEWBAR JUGNILL MILIM FROM XI.

2014

Case 2:15-cv-03690-ES-MAH Document 1-1 Filed 06/02/15 Page 6 of 92 PageID: 153

#### Appendix XII-B1

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# **CIVIL CASE INFORMATION STATEMENT** (CIS)

Use for initial Law Division Civil Part pleadings (not motions) under Rule 4:5-1 Pleading will be rejected for filing, under Rule 1:5-6(c),

FOR USE BY CLERK'S OFFICE ONLY	
PAYMENT TYPE: CK CG CA	
CHG/CK NO.	
AMOUNT:	1
OVERPAYMENT:	_
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RTY?    Yes    No	1
RRANT INDIVIDUAL MANAGEMENT OR	
v England Compounding 0-2419-FDS, Hon-RyetW. Zobel,	
SSI	

O TOTAL O	if information above the black bar is not completed or attorney's signature is not affixed  BATCH NUMBER:								
ATTORNEY/PRO SE NAME Jeffrey M. Keiser, Esq./Mark Zamora, Esq.				TELEPHONE (856) 354-6		COUNT	TY OF VEN	IVE	
FIRM NAME (if appli Law Office of Jel		er/The Orlar	ido Firm				DOCKET NUMBER (when evallshie)		
OFFICE ADDRESS 76 E. Euclid Ave Sulte 201 Haddonfield, NJ	•			course Parkway #2600 a, GA 30366			MENT TYPE plaint EMAND	₹ Ø Yes	□ No
NAME OF PARTY (e.		laintiff)	CAPT	ION			<del></del>		
Kenneth Chann,				neth Chann, e	tal v. Pre	mier Orthopa	edic Ass	oc., et al	
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These cases may become part of a multi-district litigation (MDL No. 2419) In Re New England Compounding Pharmacy, Inc., Products Liability Litigation, USDC, Dist. of Mass., MDL No 1:13-MD-2419-FDS, Hon, Ryand. Zobel, USDJ									
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l certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents pubmitted in the future in accordance with Rule 1;38-7(b).									
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Effective 08-19-2013, CN 10517-English

Case 2:15-cv-03690-ES-MAH Document 1-1 Filed 06/02/15 Page 7 of 92 PageID: 154

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Side 2	•		DRMATION STATEMENT (CIS) ngs (not motions) under Rule 4:5-1
CASE TYPES	(Choose one and enter number of case	type	in appropriate space on the reverse side.)
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502	BOOK ACCOUNT (debt collection matters only)	•	
508	OTHER INSURANCE CLAIM (including declarated PIP COVERAGE	ory Juc	igment actions)
510 511	UM or UIM CLAIM (coverage issues only) ACTION ON NEGOTIABLE INSTRUMENT		
512	LEMON LAW SUMMARY ACTION		•
802	OPEN PUBLIC RECORDS ACT (summary action	n)	
999	OTHER (briefly describe nature of action)		
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305	- 300 days' discovery CONSTRUCTION		
509 599	EMPLOYMENT (other than CEPA or LAD) CONTRACT/COMMERCIAL TRANSACTION		
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303 508	MT. LAUREL COMPLEX COMMERCIAL		
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266	HORMONE REPLACEMENT THERAPY (HRT) ACCUTANE/ISOTRETINOIN		PRUDENTIAL TORT LITIGATION REGLAN
274	RISPERDAL/SEROQUEL/ZYPREXA	290	POMPTON LAKES ENVIRONMENTAL LITIGATION
279	ZOMETA/AREDIA GADOLINIUM	292	PELVIC MESH/GYNECARE PELVIC MESH/BARD
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— Putative Class Action

Title 59

Case 2:15-cv-03690-ES-MAH Document 1-1 Filed 06/02/15 Page 8 of 92 PageID: 155

Law Office of Jeffrey M. Keiser (Attorney ID # 014481974) 76 E. Euclid Ave. Suite 201 Haddonfield, New Jersey 08033

Attorneys for Plaintiffs

KENNETH CHANN SR., LAURA CHANN, :
EMIKO KANESHIKI, JOSEPH LANGLEY, :
ELDEAN LANGLEY, SAMUEL ELWELL, :
HELEN ELWELL, EDWARD HIRALDO, :
and MARILYN HIRALDO (MASONET) :

Plaintiffs.

V,

Premier Orthopaedic Associates Surgical Center, LLC; Premier Orthopaedic and Sports Medicine Associates of South Jersey, LLC, d/b/a Premier Orthopaedic and Sports Medicine Associates; Kimberley Yvette Smith, M.D. (a/k/a/Kimberley Yvette Smith-Martin, M.D.); John B. Catalano, M.D.; Thomas A. Dwyer, M.D., Nitesh Bhagat, M.D., Barry J. Cadden; Gregory Conigliaro; Lisa Conigliaro Cadden; Douglas Conigliaro; Carla Conigliaro; Glenn A. Chin; Ameridose, LLC; GDC Properties Management, LLC; Medical Sales Management, Inc.; Medical Sales Management SW, Inc.; ARL Bio Pharma, Inc. D/B/A Analytical Research Laboratories, Liberty Industries, Inc.; UniFirst Corporation, (d/b/a "Uniclean Cleanroom Services"); John Does (1-10) fictitious unknown individuals; John Doe(s) Corporations (1-100) fictitious unknown corporations; JOHN DOE(S) Business Entities (1-100), fictitious unknown non corporation business entities; and John Doe(s), M.D. (1-100) fictitious unknown medical doctors.

Defendants.

SUPERIOR COURT OF NEW JERSEY LAW DIVISION ESSEX COUNTY

DOCKET NO.

CIVIL ACTION

.7568-14

COMPLAINT AND JURY DEMAND

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Plaintiffs, Kenneth Chann, Laura Chann, Emiko Kaneshiki, Joseph Langley, Eldean Langley, Edward Hiraldo, Marilyn Hiraldo, Samuel Elwell, and Helen Elwell sue Defendants and allege:

#### I. INTRODUCTION

- This is a lawsuit for personal injuries caused by the administration of recalled drugs administered to the Plaintiffs and as alleged below, named in this Complaint.
- 2. In 2012, an outbreak of fungal meningitis injured people in more than 20 states, including New Jersey. More than 750 people have been diagnosed with serious illnesses and thousands more live in fear of contracting the disease and the prospect of suffering painful injuries, testing and treatment. This preventable outbreak originated from medications compounded and distributed by the now bankrupt New England Compounding Pharmacy, Inc. d/b/a "New England Compounding Center" ("NECC"). The medications included preservative free methylprednisolone acetate ("MPA") that were improperly compounded, sterilized, tested, packaged, marketed, labeled, dispensed, acquired, prescribed and administered by various entities as described below.
- 3. The Food and Drug Administration ("FDA") and the Centers for Disease Control ("CDC") identified fungus in lots of NECC supplied injectable steroids, and specifically identified three MPA lots NECC had compounded in batch between May and August of 2012. The FDA and CDC concluded that the MPA, which was compounded at the NECC compounding pharmacy facility in Framingham Massachusetts, was the cause of the aforementioned injuries and deaths. The NECC facilities, and especially its so called "clean room," were deplorably unclean, unsanitary and unsterile. These conditions

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combined with other omissions by other entities - were the source of fungus that contaminated NECC's compounded medications. The blatant disregard for even the most basic sanitary and sterility obligations by NECC, as well as its directors officers, employees, together with the wrongful conduct, omissions and activities of other actors and entities associated with or responsible for NECC's facility's deplorable condition and/or the dispensing and distribution of contaminated drugs, as described herein, together with the Health Care Providers' and other actors' woefully insufficient due diligence, vetting, inspection, testing, warning, disclosure, informed consent, overt misrepresentations, and knowing dispensing of drugs compounded under the specter of such wrongful conduct by NECC and others, all led and substantially contributed to a national epidemic of fungal meningitis, as well as were substantial contributing factors to each of the named Plaintiff's injuries and losses described below.

- 4. Multiple vials of MPA, along with other medications compounded at the NECC facilities have been recalled, but the recall was too late for the Plaintiffs and for many others who were injected with a fungal contaminated medicine and suffered injuries or death from one of the largest latrogenic epidemics in United States' history.
- 5. The Health Care Provider Defendants named herein are a significant and contributing part of the cause of this epidemic and resulting injuries. The Health Care Provider Defendants, among other things, negligently selected NECC as a compounding pharmacy for a difficult medication to compound in a preservative free form, and repeatedly ordered preservative free MPA in so called office supply quantities from NECC in contravention of applicable Massachusetts pharmacy dispensing laws. Among the compounded medication the Health Care Providers obtained from NECC were vials

of preservative free MPA dispensed from one or more lots of the three (3) contaminated lots of MPA laden with fungus.

- 6. MPA drawn from these vials was then, and without proper and necessary disclosure of the nature and source of the compounded medication, and without obtaining proper and intelligent informed consent, was injected into Plaintiffs' bodies on or the dates stated below by Health Care Providers as noted as part of recommended pain management treatment for conditions each Plaintiff was suffering.
- 7. As a result of the administrations of the contaminated MPA as alleged below each Plaintiff sustained injuries as more particularly described below.

#### III. PARTIES

- 1. Each Plaintiff Kenneth Chann, Laura Chann, Samuel Elwell, Helen Elwell, Emiko Kaneshiki, Joseph Langley, Eldean Langley, Edward Hidalgo, and Marilyn Hiraldo (Masonet) is a citizen and resident of New Jersey.
- 2. Plaintiff Kenneth Chann is a resident of New Jersey, residing at 855 E. Gordon Road, Vineland, Cumberland County, New Jersey. Laura Chann is the lawful spouse of Kenneth Chann, and she resides at the same address.
- 3. Kenneth Chann had ongoing back pain, and sought out medical care. He underwent injections with products made by NECC, and had the products put in his body on August 20, 2012. The doctors who injected the product were located at the former SJ Regional Medical Center, now known as Inspira Health Network, located at 1505 West Sherman Avenue, Vineland, New Jersey. As a result of receiving these tainted products, Chann developed headaches, avascular necrosis of the left hip, and ongoing severe hip

pain that is permanent. He suffers anxiety, emotional pain and suffering, and physical pain and suffering.

- 4. Plaintiff Joseph Langley is a citizen and resident of New Jersey, residing at 2032 Fairton Road, Millville, Cumberland County, New Jersey. Plaintiff Eldean Langley is the lawful spouse of Joseph Langley, and she resides at that same address.
- 5. Plaintiff Joseph Langley underwent several procedures for ongoing pain, including but limited to a pedicle screw fixation of the L5 and S1. He was injected with NECC-made products on or about April 29, 2012, May 17, 2012 and August 30, 2012. He was injected with such products by one or more of the Defendants at Premier and via Dr. Smith-Martin, at the following location: South Jersey Regional Medical Center now known as Inspira Health Network, located at 1505 West Sherman Avenue, Vineland, New Jersey. He underwent a lumbar puncture on October 12, 2012. He has suffered chest tightness, numbness of his extremities, and light sensitivity, among other symptoms. He also developed a left axilla abscess, anxiety, and loss of the enjoyment of life because of the administration of the stated products.
- 6. Plaintiff Edward Hiraldo is resident of the State of New Jersey. He resides at 1 JFK Boulevard, Apartment 28-F, Somerset, New Jersey, Middlesex County. The lawful spouse of Hiraldo is Marilyn Hiraldo (Masonet) and she resides at that address.
- 7. Plaintiff Edward Hiraldo had pre-existing back pain for several years. In 2012 he was injected with NECC products while a patient at Edison Surgical Center, in Edison New Jersey. He received such injections in April, May and August of 2012. As a result, he underwent testing for fungal meningitis. He suffers from ongoing pain, anxiety, and light sensitivity.

- 8. Plaintiff Emiko Kaneshiki is a resident of the State of New Jersey, residing at 6 Davis Drive, Bridgeton, New Jersey, in Cumberland County. She received injections on July 6 and September 21, 2012, administered by Richard Strauss, M.D. to treat ongoing back pain. Kaneshiki was administered these products at a medical facility formerly known as SJ Regional Medical Center, located at 1505 W. Sherman Avenue, Vineland, NJ. The facility is now owned as Inspira Health Networks. As a result of receiving the injections, Kaneshiki suffered from generalized backaches, decreased energy, back pain, anxiety, and emotional pain and suffering.
- 9. Plaintiff Samuel Elwell is a citizen and resident of New Jersey. His address is 12 Martin Drive, Bridgeton, New Jersey, Cumberland County. Plaintiff Helen Elwell is the law spouse of Samuel Elwell, and she resides at the same address.
- 10. Samuel Elwell was injected with at least one contaminated NECC product, receiving it on September 20, 2012. He had suffered from low back pain, and his doctor prescribed the epidural injection. The doctor who administered the product into his body was Defendant Kimberly Martin- Smith, M.D. At all times, such doctor was an employee, agent, or representative or one or more Defendants Elwell had the injections at a medical facility formerly known as SJ Regional Medical Center, located at 1505 West Sherman Avenue, Vineland, NJ 08360. The contaminated product injected in to his body caused him to suffer from fungal meningitis, arachnoiditis, pain, weakness, neuropathy, and results in his incurring more than \$500,000 in medical bills.
- 11. Defendant Inspira Health Network, Inc. ("IHNI") is a New Jersey incorporated non-profit health care organization that was formed in November 2012 by the merger of South Jersey Healthcare, Inc. and Underwood-Memorial Hospital. It is the

parent organization and owner of Inspira Medical Centers, Inc., which subsidiary owned and operated the medical health care organizations and/or facilities that prior to May 1, 2013 were known as "South Jersey Health Care" and/or "South Jersey Regional Medical Center", and after May 1, 2013 were and are today known as "Inspira Health Network", "Inspira Medical Center Vineland," and Inspira Medical Center Elmer. IHNI's principal place of business is located at 165 Bridgeton Pike, Mullica Hill, NJ 08062.

- Defendant Inspira Medical Centers, Inc., ("IMCI") is a New Jersey non-profit corporation owned and operated the medical health care organizations and/or facilities that prior to May 1, 2013 were known as "South Jersey Health Care" and/or "South Jersey Regional Medical Center", and after May 1, 2013 were and are today known as "Inspira Health Network", "Inspira Medical Center Vineland," and Inspira Medical Center Elmer. IMCI's principal place of business is located at 165 Bridgeton Pike, Mullica Hill, NJ 08062. Inspira Medical Center Vineland's (formerly "South Jersey Regional Medical Center") principal place of business is located at 1505 West Sherman, Vineland, NJ 08360.
- 13. At all times material herein Defendants IHNI and IMCI (collectively referred to hereinafter as "Inspira" or the "Inspira Defendants") acted by and through its or their employees, servants, agents, officers, directors, committees, delegates, and workers, actual, apparent or ostensible, any and all of whom were then and there acting with the course and scope of their actual or apparent duties, authority, agency or employment. Many of the relevant Inspira actors are reasonably not known to any named Plaintiff at this time and thus are among the fictitious John Doe individuals, doctors, administrators, pharmacists and organizations identified below.

- 14. At all times mentioned herein and material hereto, the Inspira Defendants each held itself or themselves, together with its or their agents, servants, workers, representatives, physicians, nurses, pharmacists, staff, contractors, medical personnel and employees out to be skillful and qualified to attend, care for, treat and render medical care and services to patients such as the named Plaintiffs.
- 15. Defendant, Premier Orthopaedic and Sports Medicine Associates of Southern New Jersey, LLC, also trading as Premier Orthopaedic (hereinafter referred to as "Premier Orthopaedic") is a corporation, medical institution and medical facility, duly organized and existing under and by virtue of the laws of the state of New Jersey, with its principal place of business located at 298 S. Delsea Drive, Vineland, NJ 08360.
- Orthopaedic, held itself and its agents, servants, workers, representatives, physicians, nurses, staff, contractors, medical personnel and employees out to be skillful and qualified to attend, care for, treat and render medical care and services to patients such as the Plaintiffs.
- 17. Defendant, Premier Orthopaedic Associates Surgical Center, LLC (hereinafter referred to as "Surgical Center") is a corporation, medical institution and medical facility, duly organized and existing under and by virtue of the laws of the state of New Jersey, with its principal place of business located at 352 Delsea Drive, Vineland, NJ 08360.
- 18. At all times mentioned herein and material hereto, Defendant, Surgical Center, held itself and its agents, servants, workers, representatives, physicians, nurses,

staff, contractors, medical personnel and employees out to be skillful and qualified to attend, care for, treat and render medical care and services to patients such as Plaintiffs.

- 19. Defendant, Kimberley Yvette Smith, M.D. a/k/a/ Kimberley Yvette Smith-Martin, M.D. (hereinafter "Dr. Smith-Martin"), is a duly licensed physician, who at all times mentioned herein, was a practicing physician in the state of New Jersey, a member of the staff of Premier Orthopaedic, Surgical Center and/or John Doe Corporations (1-100) and John Doe Business Entities (1-100). At all times material she possessed and enjoyed attending and admitting physician privileges at Inspira's medical facilities formerly known as South Jersey Regional Medical Center and South Jersey Health Care Hospital, Elmer New Jersey. At all times material she was an actually or, ostensible agent, servant, representative and/or employee of Defendant, Premier Orthopaedic, Surgical Center, Inspira, John Doe Corporations (1-100) and John Doe Business Entities (1-100).
- 20. Defendant, John B. Catalano M.D. (hereinafter "Dr. Catalano"), is a duly licensed physician, who at all times mentioned herein and material hereto, was a practicing physician in the state of New Jersey, a member of the staff of Premier Orthopaedic, Surgical Center and/or John Doe Corporations (1-100) and John Doe Business Entities (1-100). At all times material she was an actually or, ostensible agent, servant, representative and/or employee of Defendant, Premier Orthopaedic, Surgical Center, Inspira, John Doe Corporations (1-100) and John Doe Business Entities (1-100).
- 21. Defendant, Thomas Dwyer, M.D. (hereinafter "Dr. Dwyer"), is a duly licensed physician, who at all times mentioned herein and material hereto, was a practicing physician in the state of New Jersey, a member of the staff of Premier

Orthopaedic, Surgical Center and/or John Doe Corporations (1-100) and John Doc Business Entities (1-100) At all times material he was an actually or, ostensible agent, servant, representative and/or employee of Defendant, Premier Orthopaedic, Surgical Center, Inspira, John Doe Corporations (1-100) and John Doe Business Entities (1-100).

- 22. Defendant, Nitesh Bhagat, M.D. (hereinafter "Dr. Bhagat"), is a duly licensed physician, who at all times mentioned herein and material hereto, was a practicing physician in the state of New Jersey, a member of the staff of Premier Orthopaedic, Surgical Center and/or John Doe Corporations (1-100) and John Doe Business Entities (1-100). At all times material he possessed and enjoyed attending and admitting physician privileges at Inspira's medical facilities formerly known as South Jersey Regional Medical Center and South Jersey Health Care Regional Hospital, located in Vineland, New Jersey. At all times material ehe was an actually or, ostensible agent, servant, representative and/or employee of Defendant, Premier Orthopaedic, Surgical Center, Inspira, John Doe Corporations (1-100) and John Doe Business Entities (1-100)
- 23. At all times mentioned herein and material hereto, Drs. Smith-Martin, Dwyer and Catalano, and Bhagat (as to Chann) represented him or herself to be a competent, skillful and qualified physician, qualified to practice, attend, treat and administer medical care and treatment upon and to patients such as Plaintiffs.
- 24. Defendants Smith-Martin, Dwyer, Catalano, Bhagat, and John Doe (1-100) and/or John Doe M.D. (1-100) at all times material herein participated in the decision to obtain preservative free MPA from NECC and/or, on information and belief, signed the prescriptions and prescription order forms to acquire office supplies of

preservative free MPA from NECC used at Premier Orthopedic and/or in Surgery Center, which medication was administered to Plaintiffs.

4.

- 25. Defendants Smith-Martin, Bhagat, and John Doe (1-100) and/or John Doe M.D. (1-100) at all times material herein participated in the decision by Inspira to obtain preservative free MPA from NECC and, on information and belief, signed prescriptions and prescription order forms to acquire office supplies of preservative free MPA from NECC used at Inspira's and other medical facilities, including the facility formerly known as South Jersey Regional Medical Center, which medication was administered to each Plaintiff, as more particularly alleged herein.
- Defendants John Doe (1-100) are individuals whose true names are unknown to Plaintiffs and are being sued by Plaintiffs under fictitious names, pursuant to R.4:26-4. These defendants were employees, agents, workers, servants or officers of the named defendants or other persons and were responsible for, or engaged in, the manufacture, compounding, prescribing, formulating, dispensing, selection, ordering, billing, distribution, specification, handling, inspection and/or administration of the NECC MPA medication that is the subject of this suit. All or some of these fictitiously named defendants held themselves and their agents, servants, workers, representatives, physicians, pharmacists, administrators, nurses, staff, contractors, medical personnel and employees out to be skillful and qualified to attend, care for, treat and render medical care and services to patients such as the named Plaintiffs. These defendants were responsible for or engaged in, the manufacture, compounding, prescribing, formulating, dispensing, selection, ordering, billing, distribution, specification, handling, inspection and/or administration of the NECC MPA medication that is the subject of this suit.

- 27. Defendants John Doe(s), M.D. (1-10), are duly licensed physicians, who at all times mentioned herein and material hereto, were practicing physicians in the state of New Jersey, members of the staff of Premier Orthopaedic, and/or Surgical Center and/or Pain Management and/or John Doe Corporations (1-10) and were agents, ostensible agents, servants, representatives and/or employees of Defendants Inspira, Premier Orthopaedic, Surgical Center, John Doe Corporations (1-10) or John Doe Business Entities (1-10). These defendants were responsible for or engaged in, the prescribing, dispensing, selection, ordering, billing, distribution, specification, handling, inspection and/or administration of the NECC MPA medication that is the subject of this suit.
- 28. Defendants John Doe Corporations (1-100) and John Doe Business Entities (1-100), are corporations, limited liability organizations or entities, professional or business entities, medical facilities and/or medical practice groups, duly organized and existing under and by virtue of the laws of the Commonwealth of Massachusetts, the state of New Jersey, or other jurisdictions with their principal places of business at unknown addresses, whose true names are unknown to Plaintiffs and are being sued by Plaintiffs under fictitious names, pursuant to R.4:26-4. These defendants were responsible for or engaged in the manufacture, compounding, prescribing, formulating, dispensing, selection, ordering, billing, distribution, specification, handling, inspection and/or administration of the NECC MPA medication that is the subject of this suit.
- 29. Collectively defendants Inspira, Premier Orthopaedic, Surgical Center, Dr. Smith-Martin, Dr. Catalano, Dr. Bhagat, and Dr. Dwyer, together with all or some of the John Does (1-100) John Doe Corporations (1-100), John Doe Business Entities (1-100), and John Doe(s), M.D. (1-100), are referred to herein as the "Health Care Providers."

- 30. Defendant Ameridose, LLC, ("Ameridose") is a Massachusetts limited liability company organized and existing under the laws of the Commonwealth of Massachusetts with a principal place of business at 203 Flanders Road, Westborough, Massachusetts, 01581. The managers of Ameridose are Gregory Conigliaro and Barry Cadden.
- 31. Defendant GDC Properties Management, LLC, ("GDC") is a Massachusetts limited liability company organized and existing under the laws of the Commonwealth of Massachusetts with its principle place of business at 701 Waverly Street, Framingham, Massachusetts 01702.
- 32. Defendant Medical Sales Management, Inc., ("MSM") is a Massachusetts corporation organized and originated under the laws of the Commonwealth of Massachusetts with its principal place of business at 697 Waverly Street, Framingham, Massachusetts 01702. Defendant Douglas Conigliaro is the President and a Director of MSM and in such capacity actively participated in, controlled and/or directed its operations and activities. Defendant Barry Cadden is the Treasurer and a Director of MSM. Gregory Conigliaro is the Secretary and a Director of MSM.
- 33. Defendant Medical Sales Management SW, Inc., ("MSMSW") is a Massachusetts corporation organized and originated under the laws of the Commonwealth of Massachusetts with its principal place of business at 697 Waverly Street, Framingham, Massachusetts 01702. Douglas Conigliaro is the President and a Director, Barry Cadden is the Treasurer and a Director, Gregory Conigliaro is the Secretary and a Director and Lisa Conigliaro Cadden is a Director.

- 34. Defendant Barry J. Cadden ("Barry Cadden") is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts 02093, and is a citizen and resident of the Commonwealth of Massachusetts. Barry Cadden is the President of NECC. At least until October 2012, Barry Cadden was NECC's licensed Pharmacist Manager of Record, as that term is defined by Massachusetts' regulation, 247 CMR 2.00, and upon information and belief, he compounded MPA at NECC. Barry Cadden was also a founder and Manager of Ameridose and was involved in Ameridose's day-to-day operations. Barry Cadden was also the Treasurer and Director of MSM and MSMSW.
- 35. Defendant Gregory Conigliaro ("Gregory Conigliaro") is an individual person residing at 1 Mountain View Drive, Framingham, Massachusetts 01701. Gregory Conigliaro is a principal owner and the general manager of NECC, as well as NECC's Treasurer, Secretary, Vice President, Registered Agent, and one of its Directors. Gregory Conigliaro provided financial advice, oversaw operations, and regularly appeared in the NECC facility. Gregory Conigliaro is also the founder and a Manager of Ameridose and involved in Ameridose's day-to-day operations. Gregory Conigliaro is also Secretary and Director of MSM and MSMSW.
- 36. Defendant Lisa Conigliaro Cadden ("Lisa Cadden") is an individual person residing at 13 Manchester Drive, Wrentham, Massachusetts 02093. Lisa Cadden is a board member, Director and, at least until October 2012, a pharmacist at NECC. Lisa Cadden, upon information and belief, compounded drugs and was involved in the day-to-day operations of NECC.
- 37. Defendant Douglas Conigliaro ("Douglas Conigliaro") is an individual person residing at 15 Hale Drive, Dedham, Massachusetts 02026. Douglas Conigliaro is

Director and President of MSM and MSMSW. Douglas Conigliaro provided advice, oversaw day-to-day operations and regularly appeared in the MSM/MSMSW facility.

- 38. Defendant Carla Conigliaro ("Carla Conigliaro") is an individual person residing at 15 Hale Drive, Dedham, Massachusetts 02026. Carla Conigliaro is one of the Directors of NECC and the wife of Douglas Conigliaro.
- 39. Defendant Glenn A. Chin ("Chin") is an individual person residing at 173 Mechanic Street, Canton, Massachusetts 02021. At least until October 2012, Glenn Chin was a pharmacist at NECC. Chin, upon information and belief, compounded drugs, including MPA, at NECC.
- 40. Defendant Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Chin, Ameridose, LLC, GDC Properties Management, LLC, Medical Sales Management, Inc., Medical Sales Management SW, Inc., are sometimes collectively referred to as the "NECC Related Parties."
- 41. Defendant ARL Bio Pharma, Inc. d/b/a Analytical Research Laboratories ("ARL") is an Oklahoma corporation organized and domesticated under the laws of the State of Oklahoma with a principle place of business at 840 Research Parkway, Suite 546, Oklahoma City, Oklahoma 73104. Thomas C. Kupiec is the Chief Executive Officer and registered agent of ARL.
- 42. Defendant Liberty Industries, Inc. ("Liberty") is a Connecticut corporation with its principal place of business at 133 Commerce Street, East Berlin, Connecticut 06023. Liberty designs, manufactures, distributes, and installs cleanrooms and contamination control supplies both in the United States and worldwide. Liberty manufactured, constructed, installed, and/or designed all NECC and Ameridose

cleanrooms at the Framingham, Massachusetts facility. The cleanrooms manufactured, constructed, installed and/or designed for NECC and/or Ameridose contained defects that made them unsuitable for their intended use and were a direct and proximate cause of injury to each Plaintiff, as alleged.

- organized and existing under and by virtue of the laws of the State of Massachusetts, with its principal place of business located at 68 Jonspin Road, Wilmington, MA 01887 and place of business in Essex County, New Jersey at 8 Hixon Pl, Maplewood, NJ 07040. "UniClean" is a division of UniFirst. UniFirst's corporate mission is to be recognized as the quality leader in the cleaning and garment industry. UniFirst also represents that its services will "improve the safety and cleanliness" of a business facility when hired to perform services there. UniFirst at all material times contracted with NECC to provide cleaning services, including cleaning the "cleanrooms" used to manufacture and/or compound drugs, including NECC Contaminated Drugs.
- 44. At all times material herein, all defendants acted by and through their respective agents, officers, employees and servants, actual, apparent or ostensible, any and all of whom were then and there acting within the course and scope or their agency, authority, duties or employment, including, but not limited to, John Does (1-10), John Doe Corporations (1-10), John Doe Business Entities (1-10), and John Doe(s), M.D. (1-10) whose identities are presently unknown.

# IV. JURISDICTION AND VENUE

45. Jurisdiction is proper in that many of the materials actions as well as the tortious harm occurred here in New Jersey.

46. Venue for this action is proper in Essex County, as Defendant UniFirst does business under the trade name "Uniclean" and many place of business in Essex County, New Jersey at 8 Hixon Pl, Maplewood, NJ 07040.

#### V. FACTS COMMON TO ALL COUNTS

# NECC's Chapter 11 Bankruptcy Proceeding

- 47. On December 21, 2012, NECC filed a petition for Bankruptcy protection under Chapter 11 of the Bankruptcy Code which is pending and captioned as *In re: New England Compounding Pharmacy, Inc., Debtor*, United States Bankruptcy Court for the District of Massachusetts Case No. 12:19882 HJB. A United States Trustee was subsequently appointed to administer the Bankruptcy Estate.
- 48. This case is related to NECC's Bankruptcy case because the prosecution and/or outcome of the proceeding could have an effect on the bankruptcy estate.
- 49. Upon information and belief, (i) NECC has express contractual indemnification obligations to among others, the NECC Related Parties, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Carla Conigliaro, Douglas Conigliaro, Glenn Chin, GDC, MSM and MSMSW, (ii) some if not all of the aforementioned individuals are insureds under NECC's insurance policies and (iii) NECC and the NECC Related Parties, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Carla Conigliaro, Douglas Conigliaro, Glenn Chin, GDC, MSM and MSMSW, all have contribution, indemnification and/or other reimbursement claims against as against each other.
- 50. Adversary proceedings seeking recovery of damages for the benefit of the bankruptcy estate and its unsecured creditors have been filed in NECC's bankruptcy

against several of the NECC Related Parties (Barry Cadden, Lisa Cadden, Gregory Conigliaro, Carla Conigliaro, GDC, and MSM).

#### Multi-District Litigation Proceedings

51. Lawsuits alleging death or injury based on contaminated MPA have been filed around the country. On February 12, 2013, the Judicial Panel on Multidistrict Litigation (MDL No. 2419) issued an order under 28 U.S.C. § 1407 transferring various federal court proceedings to the United States District Court for the District of Massachusetts for coordinated or consolidated pretrial proceedings (the "MDL Court"). The transferred actions are pending in the MDL Court in the Multidistrict Litigation action styled: In re: New England Compounding Pharmacy, Inc. Products Liability Litigation, United States District Court, District of Massachusetts, MDL No. 1:13-md-2419-FDS. The transferred cases have been assigned to the Honorable Rya W. Zobel, United States District Judge, for pre-trial proceedings and coordination. This case is a related case to those and subject to transfer to the MDL per order of the MDL Court relating to transfer of cases related to the NECC MDL and Chapter 11 Bankruptcy.

## NECC's compounding operations and activities of the NECC Related Parties, ARL, Liberty and UniClean

- 52. NECC was a compounding pharmacy that compounded, distributed and/or sold drugs to pharmacies in many states throughout the United States, including New Jersey.
- 53. Upon information and belief, NECC was a privately-held company that was owned and controlled by Gregory Conigliaro, Carla Conigliaro, Douglas Conigliaro, Barry Cadden, and Lisa Cadden. At all times material these parties had the ability and

power to affect changes and corrective actions relating to NECC's conduct and omissions that are relevant to this matter.

- 54. At least until October 2012, Barry Cadden was a licensed pharmacist. In addition to being NECC's President, Barry Cadden was also NECC's licensed Pharmacist Manager of Record. Upon information and belief, Barry Cadden compounded medications, including MPA, at NECC.
- 55. "Manager of Record" or "Pharmacist Manager of Record," as defined by Massachusetts Regulation, 247 CMR 2.00, "means a pharmacist, currently registered by the [Massachusetts] Board [of Registration in Pharmacy] pursuant to 247 CMR 6.07, who is responsible for the operation of a pharmacy or pharmacy department in conformance with all laws and regulations pertinent to the practice of pharmacy and the distribution of drugs."
- 56. One of the Massachusetts regulations promulgated by the Massachusetts Board of Registration in Pharmacy pertinent to NECC's operation as a compounding pharmacy mandated that "[t]he premises of the pharmacy or pharmacy department shall at all times be kept in a clean and sanitary manner." 247 CMR 6.02(1).
- 57. At least until October 2012, Gregory Conigliaro was involved in comanaging the day-to-day operations of NECC, MSM, MSMSW, Ameridose, and GDC. At all times material herein he had the ability and power to affect changes and corrective actions relating to these entities' conduct and omissions that are relevant to this matter.
- 58. At least until October 2012, Lisa Cadden was a licensed pharmacist who, upon information and belief, compounded medications, including MPA, at NECC. She also was involved in the management of NECC and had the ability and power to affect

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changes and corrective actions relating to NECC's conduct and omissions that are relevant to this matter.

- 59. At least until October 2012, Glenn Chin was a licensed pharmacist who, upon information and belief, compounded medications, including MPA, at NECC. At all times material herein Chin had the ability and power to affect changes and corrective actions relating to NECC's conduct and omissions that are relevant to this matter, and/or or take reasonable steps and measures to prevent or ameliorate any harm happening to consumers by NECC's conduct and omissions that are relevant to this matter.
- 60. According to an application signed by Gregory Conigliaro and filed with the Massachusetts Board of Registration in Pharmacy on May 14, 2012, Ameridose is a "distribution center to entities of common ownership currently Ameridose and NECC, as well as other Properly Licensed Facilities in the future."
- 61. Since it was formed as a limited liability company in 2006, Ameridose has been controlled by NECC. In 2005, NECC hired and paid Sophia Pasedis, a member of the Massachusetts Board of Registration in Pharmacy, to consult with NECC on the formation and establishment of Ameridose.
- 62. On April 11, 2011, Ameridose employee, Michelle Rivers, upon information and belief and at the direction of the NECC principals, requested certification for pharmacy technicians employed by NECC for use in an inspection of NECC's facilities by the Massachusetts Board of Registration in Pharmacy.
- 63. On or about August 24, 2012, Ameridose posted an employment opportunity for Registered Pharmacists to work for NECC in Framingham, Massachusetts. In the posting, potential applicants were told to contact

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"mlord@medicalsalesmgmt.com." Upon information and belief, there were many other occasions where employees of Ameridose, MSM and/or MSMSW would perform services for NECC at the direction of NECC's principals.

- 64. Between 2006 and the present, Ameridose and NECC would often share a booth at conferences and conventions with a single banner listing both company names. During that same time, Ameridose and NECC would hold an annual Christmas party for employees of both companies.
- 65. Both Ameridose and NECC were controlled by Conigliaro and Cadden family members. MSM and/or MSMSW printed materials for and marketed both NECC's and Ameridose's products, including MPA. One former employee of MSM and/or MSMSW has reportedly stated: "I didn't think there was any difference [between Ameridose and NECC]."
- 66. Through September 2012, both NECC and Ameridose used MSM and/or MSMSW for sales and marketing functions. NECC's privacy policy on its website referred to the "Ameridose Privacy Policy." In 2012, NECC salespersons recommended NECC's "sister company," Ameridose, for drug compounds that NECC did not have available.
- 67. MSM and/or MSMSW shared office space owned by GDC Properties with NECC in Framingham, Massachusetts.
- 68. According to ARL's Internet website, "ARL is a dynamic contract research organization providing high quality analytical work and problem solving to the pharmaceutical industry."

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- 69. According to ARL's Internet website, ARL offers "a full range of laboratory services, both analytical and microbiological" and "strives to collaborate with the compounding pharmacists, by helping them improve the quality of the compounds they prepare through meticulous analysis, data interpretation and troubleshooting."
- 70. ARL also states on its Internet website that it follows "USP monographs/general chapters[,]" and that it has a formal Quality Assurance Program in compliance with "USP monographs/general chapters[.]"
- 71. In marketing its laboratory testing services to compounding pharmacies such as NECC, ARL states: "[y]our customers have high expectations of you and your compounding pharmacy. You offer exceptional service and quality preparations that are compounded to exacting specifications. You should expect nothing less from the testing laboratory you entrust." (emphasis is original).
- 72. In marketing its laboratory testing services to compounding pharmacies such as NECC, ARL states that ARL's "[t]esting methods and technologies [are] unparalleled in the market today[.]" (emphasis in original).
- 73. Upon information and belief, ARL provided and was paid for sterility testing services and information to NECC for its compounded medications, including MPA.
- 74. With respect to its sterility tests, ARL, on its Internet website, states: "We examine each sterility test for growth at days 2, 3, 7 and 14 and log the results. If a test shows no evidence of microbial growth in either media over the 14 day incubation period, then it complies with the test for sterility. A preliminary sterility report is available after 72 hours of incubation."

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- 75. At all times material herein, ARL knew or had reason to know that (a) its testing and test results relating to NECC products, including MPA, were commissioned and intended for the protection of patients who were to be administered NECC's compounded medications; (b) that its test results would be relied upon and used by NECC in dispensing the medication to doctors and medical facilities ordering and administering NECC's medications; (c) that doctors depended upon and would rely on ARL's test results in determining to administer NECC's compounded medications; and (d) NECC would distribute or share ARL's test results with physicians and/or hearth care facility decision makers in connection with NECC's marketing and/or dispensing of its compounded medications, including MPA.
- 76. GDC, whose name is an acronym for "Gregory D. Conigliaro," owns the real property and is responsible for maintenance and structural improvements at 685-705 Waverly Street, Framingham, Massachusetts.
- 77. From 1998 until at least October 2012, GDC leased a portion of the premises at Waverly Street to NECC, MSM and MSMSW.
- 78. In an online posting for a property management position at GDC, which appeared on or before October 25, 2012, GDC stated that it "owns an 88,000 square foot facility on seven acres in downtown Framingham. GDC currently has eight major tenants." GDC describes one of the duties and responsibilities of the GDC property manager as follows: "Insure all tenants operate their businesses in accordance with facility, local [and] state ...rules and regulations."
- 79. GDC maintained and/or exercised a high degree of control over the premises leased by NECC.

- 80. Liberty manufactured, constructed, installed, and/or designed all NECC and Ameridose cleanrooms at the Framingham, Massachusetts facility. The cleanrooms manufactured, constructed, installed and/or designed for NECC and/or Ameridose contained defects that made them unsuitable for their intended use and were a direct and proximate cause of injury to Plaintiffs.
- 81. UniFirst at all material times contracted with NECC to provide cleaning services, including cleaning the "cleanrooms" used to manufacture and/or compound drugs, including NECC Contaminated Drugs.

#### The 2012 MPA Fungal Infection Epidemic

- 82. MPA is a steroid medication that is used, *inter alia*, to treat joint, neck and back pain. MPA is commonly administered via spinal-area injection to patients with neck and back pain.
- 83. Until October 2012, NECC, Ameridose, ARL, Barry Cadden, Lisa Cadden and Glenn Chin compounded, tested, marketed, dispensed and/or distributed MPA, including a purported preservative free sterile version that is difficult to compound and carries substantial risks of contamination, adulteration and/or misbranding.
- 84. GDC and Gregory Conigliaro knew that NECC was compounding MPA, including a purported preservative free version, at NECC's 697 Waverly Street facility, and further knew that this medication was injected into humans and was required to be sterile.
- 85. Until October 2012, NECC compounded MPA, including a preservative free version, at its facility in Framingham, Massachusetts, and NECC sold MPA, including a preservative free version, to health care providers in more than 20 states.

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across the country, including to Inspira and Surgical Center in New Jersey, directly and/or through Ameridose, MSM and/or MSMSW

- 86. On September 21, 2012, the CDC was notified by the Tennessee Department of Health of a patient with the onset of meningitis following an epidural steroid injection. It was later determined that the patient had fungal meningitis.
- 87. According to the CDC, fungal meningitis occurs when the protective membranes covering the brain and spinal cord are infected with a fungus. Fungal meningitis is rare and is usually caused by the spread of a fungus through blood to the spinal cord. Fungal meningitis is not transmitted from person to person.
- 88. According to the CDC, symptoms for meningitis include the following: new or worsening headache, fever, sensitivity to light, stiff neck, new weakness or numbness in any part of the body, slurred speech and increased pain, redness or swelling at the injection site. Death may result from meningitis.
- 89. According to the CDC, symptoms of fungal meningitis are similar to symptoms of other forms of meningitis; however, they often appear more gradually and can be very mild at first. In addition to typical meningitis symptoms, like headache, fever, nausea, and stiffness of the neck, people with fungal meningitis may also experience confusion, dizziness, and discomfort from bright lights. Patients may just exhibit one or two of these symptoms.
- 90. On or about September 26, 2012, NECC recalled the following lots of methylprednisolone acetate (PF) 80mg/ml that it had compounded and sold: Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #05212012@68, BUD 11/17/2012; Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #06292012@26,

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BUD 12/26/2012; and Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #08102012@51, BUD 2/6/2013. The "PF" denotes preservative free. The number in the Lot# denotes the date of the lot's compounding.

- 91. The FDA has identified Inspira's Vineland and Elmer facilities and Surgery Center as among the health care facilities that received vials of contaminated MPA that were subject to the September 2012 recall. Premier's Surgical Center and Inspira's "South Jersey Regional Medical Center" are also the locations where the stated were separately injected with NECC's contaminated MPA. On information and belief, each Plaintiff was administered MPA from one or more of NECC's three recalled lots.
- 92. On information and belief, including the purported prescription records provided by NECC's trustee and Inspira to the MDL PSC depository, Inspira's agents and employees regularly and customarily faxed to NECC's Massachusetts' compounding pharmacy "Prescription Order" forms for preservative free MPA. Dr. Smith-Martin is listed as the prescribing physician on many, if not the great majority, of these prescription order forms. Appearing on the prescription order form under the column "Name of Patient" are statements to "see lists". The referenced lists contained lists (often from patient schedule) of purported patients names being prescribed MPA that on information and belief were either bogus or former patient names and were not the names of patients actually being prescribed compounded medications NECC was being asked to fill and dispense in response to the prescription..
- 93. On information and belief, including the purported prescription records provided by NECC's trustee, Surgical Center also faxed to NECC's Massachusetts' compounding pharmacy NECC Prescription Order form for preservative free MPA.

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Several doctors, including Dr. Dywer may have been listed as a prescribing physician on the forms submitted by Surgery Center. The Surgery Center prescription orders list under the column "Name of Patient lists purported patients names that on information and belief may likewise have contained bogus of former patient names. Therefore each Plaintiff's name, if ever, only was listed on a prescription form once each had already been administered MPA. Such prescriptions violate Massachusetts and New Jersey pharmacy laws and would also mean that medication prescribed and dispensed for another patient was being administered to each Plaintiff.

- 94. On October 6, 2012, NECC announced that it was recalling "all products currently in circulation that were compounded at and distributed from its facility in Framingham, Massachusetts."
- 95. In NECC's October 6, 2012, press release, NECC advised that it was "notifying its customers of this recall by fax[,]" and that "[c]linics, hospitals and Health Care providers that have product which is being recalled should stop using the product immediately, retain and secure the product, and follow instructions contained in the fax notice." It was subsequent to this event that each Plaintiff was first made aware by the Health Care Providers that she had been administered NECC's contaminated steroids medications. Prior to this time she was reasonably unaware of this.
- 96. In NECC's October 6, 2012, press release, NECC explained that "[p]roducts from NECC can be identified by markings that indicate New England Compounding Center by name or by its acronym (NECC), and/or the company logo.
- 97. In addition, as the CDC, and other health care authorities, practitioners and commentators monitored and reported on developments in the exposed patient

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community, it was discovered that the problems associated with patient injections from the three recalled MPA lots are manifold, latent, insidious and long lasting, including: (a) an outbreak of localized spinal or paraspinal infections at or about the site where the MPA steroid was injected; (b) infections associated with injections into a peripheral joint space, such as a knee, shoulder, or ankle; and (c) delayed manifestation, recrudescence and relapse of diagnosed fungal meningitis and spinal, paraspinal and joint space infections and abscesses.

- 98. On or about October 3, 2012, the Massachusetts Department of Public Health ("DPH") secured the surrender of NECC's license to operate as a compounding pharmacy.
- 99. On or about October 8, 2012, at the request of DPH, Barry Cadden and Glenn Chin agreed to voluntarily cease their practice as pharmacists until at least December 31, 2012. Lisa Cadden also has agreed to voluntarily cease her practice as a pharmacist until at least December 31, 2012. Upon information and belief, none of them have practiced as a pharmacist since voluntarily ceasing their practice.
- 100. On or about October 22, 2012, the Massachusetts Board of Registration in Pharmacy authorized DPH to request the voluntary permanent surrender of the licenses of Barry Cadden, Glenn Chin, Lisa Cadden and NECC. According to DPH, "[i]f the three pharmacists and NECC do not comply, the Board authorized staff to proceed with permanent revocation."
- 101. Over the last ten years, ARL has conducted sterility testing on samples of methylprednisolone acetate compounded by NECC, including samples from Lot

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#05212012@68, BUD 11/17/2012; Lot #06292012@26, BUD 12/26/2012; and Lot #08102012@51, BUD 2/6/2013.

- 102. From May, 2012 through August 2012, NECC sent several samples of its methylprednisolone acetate to ARL for sterility testing. As one example, on or about May 21, 2012, NECC sent to ARL two 5ml vials of methylprednisolone acetate from a batch of 6,528 vials that came from Lot 05212012@68, which had been compounded by NECC in one lot on May 21, 2012.
- 103. On May 22, 2012, ARL received and tested the two 5ml vials of methylprednisolone acetate that NECC sent to ARL on or about May 21, 2012. ARL sent to NECC a Microbiology Report dated May 25, 2012, which stated that the two vials had been tested on May 22, 2012.
- 104. ARL's May 25, 2012 Microbiology Report to NECC stated that the "preliminary" results from the sterility test using test method USP 71 showed that the two 5ml vials of methylprednisolone acetate that NECC sent to ARL on or about May 21, 2012, were "sterile." ARL's report to NECC further noted that the preliminary results were observed "after approximately 72 hours of incubation."
- 105. Pursuant to the protocols of test method USP 71, sterility testing on a batch of more than 6,000 vials of methylprednisolone acetate should have been conducted on at least 20 vials from the batch.
- 106. On or about August 10, 2012, NECC caused one 5ml vial of methylprednisolone acetate to be sent to ARL for sterility testing from a batch of several thousand vials from Lot #08102012@51, BUD 2/6/2013.

- 107. The Microbiology Reports issued by ARL to NECC between May, 2012 and September 2012 concerning the sterility testing of methylprednisolone acetate indicated that the sterility tests performed by ARL were to be conducted in compliance with USP 71.
- 108. During the summer of 2012, MSM and/or MSMSW sales representatives, on behalf of NECC and Ameridose, distributed copies of the May 25, 2012, ARL Microbiology Report concerning the testing of the vials of methylprednisolone acetate from Lot 05212012@68 to customers and/or potential customers in a packet of marketing materials intended to highlight the safety and sterility of the methylprednisolone acetate compounded by NECC.
- 109. ARL was well aware of the sterility risks posed by compounding pharmacies, specifically including the sterility risks posed by NECC's compounding practices.
- 140. In 2002, ARL found that four samples of a steroid compounded by NECC were contaminated with potentially deadly endotoxins.
- 111. In 2005, ARL's Chief Executive Officer, Thomas Kupiec ("Kupiec"), wrote in a published article that "there have been reports of tragedies resulting from a lack of quality control in the compounding pharmacy."
- 112. In 2007, Kupiec also recognized the dangers of not testing a sufficient number of samples when he wrote in a published article that "one of the recognized limitations of sterility testing is sample size."
- 113. In May 2007, the FDA issued a consumer update entitled, "The Special Risks of Pharmacy Compounding[,]" which stated that there had been "more than 200

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adverse events involving 71 compounded products since 1990. Some of these instances had devastating repercussions." All defendants either knew or had reason to know of this FDA guidance publication.

- 114. In 2007, despite being aware of the risks to human health posed by compounding pharmacies, Kupiec advocated for relaxing the USP Quality Assurance Standards for compounding pharmacies. Noting USP 71's requirements of "a minimum number of articles to be tested in relation to the number of articles in the batch" and a "14-day quarantine of the drug to await final test results[,]" Kupiec wrote in a 2007 published article that there should be "separate standards for compounding pharmacies and manufacturers."
- 115. While the requirements of USP 71 were not relaxed for compounding pharmacies after Kupiec's 2007 published article, ARL allowed compounding pharmacies such as NECC to submit an inadequate number of samples for sterility testing, which practice did not comply with USP 71 requirements.
- 116. On information and belief, other testing laboratories that perform sterility testing on drugs compounded by compounding pharmacies request double the number of samples required by USP 71.
- 117. Between January 2012 and August 2012, NECC's environmental monitoring program for its compounding facility yielded findings of numerous microbiological isolates (bacteria and mold) within the so called "Clean Room" at NECC's facility used for the production of MPA. NECC, Ameridose, GDC, MSM and/or MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin knew or should have known of these findings.

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- 118. NECC, Ameridose, GDC, MSM and/or MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin failed to investigate the findings, cause(s) and source(s) of these isolates and made no effort to identify the isolates.
- 119. NECC, Ameridose, GDC, MSM and/or MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin failed to perform any product assessments for the products made in the "Clean Room" where the isolates were found.
- 120. NECC, Ameridose, GDC, MSM and/or MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin failed to take any corrective actions or measures with regards to the isolates that were found.
- 121. Despite the findings of these isolates, NECC continued to compound preservative free MPA, and Ameridose, MSM and/or MSMSW continued to distribute marketing materials to customers and potential customers touting the cleanliness of the NECC laboratories.

## THE NECC RELATED PARTIES IGNORED SAFETY STANDARDS BY PRODUCING DRUGS IN A NON-COMPLIANT FACILITY

122. The Massachusetts Department of Public Health and FDA investigators identified serious deficiencies and significant violations at NECC that placed the public's health and safety at risk. Each Agency has released reports on Defendants' longstanding widespread disregard for safety. Some examples follow. The conditions were so bad, the FDA issued a Form 483 identifying eight pages of observed conditions or practices that may indicate violations of the Federal Food, Drug and Cosmetic Act, or related

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regulations. The findings reveal repulsive conditions where bacteria and mold fester throughout the NECC facility and equipment.

- 123. In early October 2012, FDA investigators located fungal contamination in a sealed vial of MPA at NECC's facilities on GDC's property. The FDA's findings prompted NECC to recall 17,676 single-dose vials of MPA.
- 124. Even though NECC recalled the MPA in early October, thousands (estimated to be over 14,000) of people at outpatient clinics and similar facilities in more than 20 states were injected with the steroid between July and September 2012, including each Plaintiff.
- 125. The Massachusetts Department of Public Health ("DPH") investigators, in collaboration with investigators from the FDA, investigated NECC and released preliminary findings on October 23, 2012.
- 126. As an initial matter, the DPH stated: "[u]pon beginning the joint on-site investigation of NECC early in this outbreak, DPH and FDA investigators identified serious deficiencies and significant violations of pharmacy law and regulations that clearly placed the public's health and safety at risk."
- 127. In its preliminary findings the DPH found: "[d]uring the facility inspections, investigators documented serious health and safety deficiencies related to the practice of pharmacy." The DPH noted:
  - a. NECC distributed two of the recalled lots of methylprednisolone acetate (PF) 80 MG/ML prior to receiving results of sterility testing:

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- a. Lot 06292012@26 was prepared on June 29, 2012. Final sterility testing was completed on July 17, 2012. Two shipments of product were made prior to the final sterility tests results being received.
- b. Lot 08102012@51 was prepared on August 10, 2012. Final sterility testing was completed on August 28, 2012. Eleven shipments of product were made prior to the final sterility tests results being received.

b. Final sterilization of product did not follow proper standards for autoclaving (sterilization through high pressure steam) pursuant to United States Pharmacopeia Standard 797 ("USP 797") and NECC's own Standard Operating Procedures. Examination of NECC records indicated a systemic failure to keep products in the autoclave for the required minimum 20-minute sterilization period necessary to ensure product sterility.

- c. NECC did not conduct proper validation of autoclaves pursuant to USP
   797. NECC failed to test their autoclaves to ensure proper function.
- d. Visible black particulate matter was seen in several recalled sealed vials of methylprednisolone acetate from Lot 08102012@51.
- e. Powder hoods, intended to protect pharmacists from inhaling substances during medication preparation, within the sterile compounding area were not thoroughly cleaned pursuant to USP 797. Residual powder was visually observed within the hood during inspection. This contamination may subsequently lead to contamination of compounded medications.

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f. Condition of "Tacky" mats, which are used to trap dirt, dust, and other potential contaminants from shoes prior to clean room entry, violated the USP 797. Mats were visibly soiled with assorted debris.

g. A leaking boiler adjacent to the requisite clean room created an environment susceptible to contaminant growth: "A pool of water was visually observed around the boiler and adjacent walls, creating an unsanitary condition; the culture results of this potential contaminant are still pending."

- 128. The inspection reports further revealed that surface samples from NECC's "clean" rooms found bacterial and mold, as did samples of various equipment and parts of the facility. Air sampling showed "1 big mold" as far back as May 29, 2012. Air sampling taken throughout the facility also found mold and bacteria present. Dozens of results exceeded the "action level." "There was no investigation conducted by the firm when levels exceeded their action limits and there was no identification of the isolates. No documented corrective actions were taken to remove the microbial contamination (bacterial and mold) from the facility."
- 129. Inspectors also noted in their reports on NECC: Environmental monitoring procedures and practices require sampling. Records showed mold and bacteria. "These results were not investigated and there was no identification of the isolates. There were no product impact assessments performed for any sterile products that were made in the hoods or glove boxes on the days the samples were taken. In addition, the firm has no evidence that any corrective actions were taken to prevent contamination of the sterile drug products."

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- 130. FDA reports indicate there were observations of greenish yellow discoloration lining the interior surface of the viewing lens within the "Inside" autoclave used for steam sterilization of various components and equipment (e.g. vials of multiple sizes, stoppers, and spin bars) used in the formulation and packaging of sterile drug products. The FDA further observed condensation along the interior surfaces of the "Outside" autoclave to collect in a pool at the base of the chamber.
- 131. The investigators also observed problems with NECC's ability to maintain its clean room, which is an enclosed space that is supposed to be designed and maintained to have a controlled environment with low levels of airborne particles and surface contamination. Production of sterile drug products in a properly functioning and maintained clean room reduces the risk of microbial contamination.
- 132. The site of NECC's production facility signaled potential contamination risks and hazards. A used mattress processing facility, also owned by the Conigliaro family, abuts and operates under the same roof as NECC's drug compounding facility. As the FDA noted in its inspection, "[t]he firm is abutted to the rear and along the left parking area by a recycling facility that handles such materials as mattresses and plastics. On 10/02/2012, the area was observed to include large equipment (e.g. excavators and freight trucks) producing airborne particulates (e.g. dust). Rooftop units serving the [NECC] firm's HVAC system were estimated to be located approximately 100 feet from the recycling facility."
- 133. The FDA observed what appeared to be white filamentous substances covering the HVAC return located behind the autoclave located in the firm's Middle Room (purportedly an ISO level 7 space). This autoclave is used for the steam

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sterilization of formulated bulk drug suspensions. The FDA further observed greenish residue covering the surface of the ceiling exposed to the filter above, within Weigh Station 3 Hood located in the firm's purported ISO 6 "Clean Room." The firm uses Weigh Station Hoods to weigh active ingredients and other raw materials utilized in the formulation of sterile drug preparations.

- 134. In sum, FDA observed bacteria and mold growing all over the firm's "sterile" facility, one which NECC repeatedly represented to customers was "state-of-theart" and used to produce "highest quality compounded medications."
- 135. MSM and/or MSMSW marketed, Ameridose distributed and ARL certified the sterility of the NECC products that were compounded in such deplorable conditions.
- 136. Liberty negligently and defectively designed, installed and repaired NECC's clean rooms and contributed to the existence of the unclean and unsatisfactory conditions at NECC, thereby contributing to the contamination of the MPA compounded by NECC.
- 137. UniFirst negligently cleaned NECC's cleanroom and in the course of same was aware of the chronic and unclean and unsatisfactory conditions at NECC, which it failed to properly clean and, importantly, failed to notify appropriate management and/or regulatory bodies of the chronic problem; thereby contributing to the contamination of the MPA compounded by NECC and/or the dispensing of contaminated medications.

THE NECC RELATED PARTIES DISREGARDED PRIOR COMPLAINTS AND INSPECTIONS BY CONTINUING IMPERMISSIBLE CONDUCT AND IGNORING SAFETY RISKS

138. The NECC Related Parties effectively ignored dozens of complaints and

warnings signs of hygiene and sterility problems from as early as April 1999.

outbreak in 2012.

139. In 2002, two patients suffered an adverse effect after taking an NECC compounded steroid used to treat joint pain and arthritis. One victim subsequently died. The FDA notified the Massachusetts' pharmacy board in October 2002 about an incident involving a drug the company had produced, methylprednisolone acctate, which is the same steroid that caused the current fungal meningitis and other associated disease

140. In 2004, an inspection report revealed that a toxin had been found in an NECC drug and that the company could not produce various records about the drug, including test results on its sterility. NECC and other Defendants failed to meet accepted standards that year for making the same steroid as involved herein.

141. A 2006 letter to NECC from Pharmacy Support Inc., an outside evaluation firm, observed that the company continued to have significant gaps in its sterile compounding operation. That same year the FDA issued warning letters to NECC. NECC and other Defendants received other warnings as well.

142. NECC and the NECC Related Parties solicited, permitted or facilitated and/or aided and abetted the solicitation of, out-of-state prescriptions for office use and used unapproved forms. NECC and the NECC Related Parties were aware of complaints regarding this practice and its improper promotional material and methods, but turned a blind eye to it all.

THE HEALTH CARE PROVIDERS EXPOSED CLAIMANT TO TOXIN CONTAMINATED NECC COMPOUNDED MPA

- 143. Between May and September of 2012, the NECC Related Parties caused numerous vials of preservative free methylprednisolone acetate to be shipped to Inspira's and Surgery Center's respective medical facilities in Vineland, New Jersey which were part of the three lots of contaminated preservative free MPA recalled by NECC. Thousands of other contaminated vials were shipped to scores of other clinics across the country.
- 144. Massachusetts law and regulations require patient specific prescriptions in order for a Massachusetts compounding pharmacy such as NECC to legally compound, fill and dispense a medication prescription regardless of the location of the patient or prescriber. Massachusetts law prohibits selling and dispensing compounded medications pursuant to so called "office supply" quantity prescriptions.
- laws and regulations but negligently, recklessly or intentionally took, authorized, permitted, failed to stop or otherwise aided and abetted NECC's disregard, violation and circumvention of applicable Massachusetts law and regulations, by directing or allowing prescribers or health care providers to supply false or fabricated prescription forms in connection with obtain NECC's compounded MPA and other prescription drugs. In the course of so doing these parties further agreed expressly, impliedly or tacitly with various NECC Related Parties named herein, to engage in overt, purposeful and malicious acts that violate or circumvent applicable Massachusetts pharmaceutical law and regulations.
- 146. The Health Care Providers were aware of these Massachusetts compounding laws and regulations but negligently, recklessly or intentionally took, authorized, permitted, failed to stop or otherwise aided and abetted NECC's disregard,

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violation and circumvention of applicable Massachusetts law and regulations, by, among other things, supplying, directing or allowing prescribers or other health care providers or administrative staff to supply false, bogus or fabricated prescription forms in connection with obtain NECC's compounded MPA and other prescription drugs. In the course of so doing these parties further agreed expressly, impliedly or tacitly with various health care providers, including the Health Care Providers named herein, to engage in overt, purposeful and malicious acts that violate or circumvent applicable Massachusetts pharmaceutical law and regulations.

# THE HEALTH CARE PROVIDERS' TREATMENT AND CARE OF PLAINTIFFS

- 147. Plaintiffs incorporate the allegations as set forth above.
- hown of the dangers of using compounded preservative free steroid drug formulations instead of such drugs that were manufactured by FDA approved manufacturers, and specifically were aware of or had reason to know of the risks and dangers of using drugs compounded by NECC. The dangers, hazards and problems entailed in administering compounded drugs, and especially the use of preservative free sterile preparations, were known to the medical profession and the subject of articles and professional guidance documents.
- 149. NECC competed in the medical marketplace on the basis of offering cheaper prices for MPA and other drugs. Such factor and consideration is believed, and therefore alleged, to have entered into and was one of the factors prompting the Health Care Providers to either obtain, or to decide and direct Inspira and/or Surgical Center to

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obtain, preservative free MPA from NECC instead of other available manufactured steroid preparations, or, alternatively, obtaining compounded MPA from local pharmacies where it could have readily visited, inspected and monitored the quality and safety of the MPA being compounded for use in epidural steroid injection ("ESI") procedures performed by the Health Care Providers at Inspira's and Surgical Center's respective New Jersey facility.

- 150. Despite the existence of professional organizations and societies that provide inspections, assessments and accreditation certifications for compounding pharmacies, NECC was not accredited by any such organization.
- preservative free MPA for its patients, including each stated Plaintiff they either failed to take or negligently performed reasonable and necessary due diligence and investigatory steps and measures necessary to vet, evaluate and determine the safety and quality of NECC's products, and, in particular, determine if NECC could properly and suitably compound, package and provide to them sterile preservative free MPA for use in steroid injection procedures, including the procedures performed on each stated Plaintiff on the stated dates.
- 152. At no time prior to the steroid injection procedures on each stated Plaintiff did any of the Health Care providers disclose, advise or inform any Plaintiff that the steroid medication going to be injected into each Plaintiff's body was not a medication manufactured by an FDA approved and inspected manufacturer, such as brand name or an FDA approved AB generic of Depo-Medrol, but rather was a knock-off medication that the Health Care Providers had obtained via mail order from a pharmacy in

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Massachusetts that was neither inspected by the FDA nor accredited by any valid compounding pharmacy accrediting body. Such information is and was objectively material information to a reasonable patient's decision to undergo an ESI or other procedure using such medication.

Health Care Providers' wrongful conduct, each Plaintiff suffered injury to and about her person, resulting in her developing fungal meningitis and being treated with potent antifungal medications, experiencing and enduring suffering, mental anguish, fright, shock, and emotional distress. The administration of fungus-contaminated steroid medication and the ensuing treatment with potent anti-fungal medications will require Plaintiff to obtain medical expenses to monitor and if necessary, treat the sequela of being administered a potentially lethal and debilitating fungus.

#### Liberty Industries, Inc.

- 154. Liberty is a designer, manufacturer, distributor and installer of cleanrooms and contamination control supplies both in the United States and worldwide.
- 155. In 2005, 2006 and 2008, Liberty manufactured, constructed, installed, and/or designed an ISO Class 7, ISO Class 6, and an ISO Class 5 cleanrooms ("the Cleanrooms"), respectively, for NECC and/or Ameridose at the Framingham, Massachusetts facility.
- 156. Upon information and belief, subsequent room additions, rework or repair (warranty or otherwise), and/or system upgrades, done by Liberty, took place within each of these Cleanrooms after certification had been issued.
- 157. The Cleanrooms manufactured, constructed, installed and/or designed for NECC/Ameridose contained defects that made them unsuitable for their intended use.

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Liberty owed a duty to Plaintiffs, to manufacture, construct, install, and/or design the

pharmaceuticals compounded within them.

158. Liberty knew, or reasonably should have known, that the Cleanrooms were defective upon certifying them ready to use and/or upon inspecting the premises after certification and/or upon subsequent addition, rework or repair of the Cleanrooms.

NECC/Ameridose Clean rooms in such a manner as to prevent the contamination of

159. Upon further information and belief, one or more of the Cleanrooms was designed with, manufactured, constructed and/or had installed faulty ceiling grids and/or used improper materials in addition to other deficiencies creating a cleanroom environment prone to pressure inconsistencies, water damage and other failings that would disrupt or destroy the cleanliness of the Cleanrooms and making them susceptible to contamination.

- and was denied repair of Liberty's defective work. In at least one cleanroom designed and installed by Liberty, a large opening in the wall provided access to a conveyor belt covered only with hanging vinyl slats. This opening provided a means of potential contamination and made it difficult to maintain the required negative air pressure.
- 161. Further, upon information and belief, Liberty had actual and/or constructive knowledge of the deficiencies in the design, manufacture, construction, and installation of the Cleanrooms, such that products compounded within them were subject to contamination.
- 162. One or more of the Cleanrooms were used to compound the NECC Contaminated Drugs administered to each Plaintiff.

- 163. The defective manufacture, construction, installation, and/or design of the Cleanrooms, and Liberty's failure to remedy the defects despite its actual and/or constructive knowledge of those deficiencies, caused each Plaintiff to suffer damages, including, but not limited to, expenses associated with the treatment of fungal meningitis and other illnesses. The defects were the direct, proximate, and foreseeable cause of damages incurred by each Plaintiff as alleged hereinabove.
- 164. Had Liberty exercised its duty to exercise reasonable conduct by properly manufacturing, designing, and certifying the Cleanrooms, none of the Plaintiffs would have suffered the damages complained of herein.

#### UniFirst Corporation.

- 165. UniClean Cleanroom Services is a division of Defendant UniFirst Corporation. UniFirst holds itself out as a service provider delivering value-added services and products to, among other industries, the medical device, pharmaceutical, and other industries that utilize cleanroom controlled environments. UniFirst represents that it offers comprehensive cleanroom cleaning and maintenance programs to help ensure that facilities are operating within specified classification goals.
- like NECC and Ameridose. UniFirst knows that particulates in cleanrooms are deposited onto surfaces such as floors, walls, work surfaces and machinery, and that these particulates may cause increases in manufacturing and product compounding reject rates. UniFirst, its agents, employees, representatives, and UniClean workers have, for many years, had actual knowledge that visible and non-visible particulate loads can also lead to product contamination safety concerns for end users. In its marketing materials Unifirst acknowledges that to reduce these risks, it is imperative that an effective cleanroom

cleaning program be implemented and maintained. UniFirst claims to follow stringent cleaning procedures and claims to employ highly-trained technicians as key components in eliminating such contamination threats.

- 167. At all times mentioned herein and material hereto, UniFirst held itself and its agents, servants, workers, representatives, personnel, and employees out to be skillful and qualified to deliver quality services and products and through the highest standards. Indeed, UniFirst itself and/or UniClean, represents that it is an ISO 9001: 2008 registered company offering services that include sterile and non-sterile garment services, and contamination control including cleanroom cleaning, fogging and environmental monitoring, among other services.
- In the company's own marketing materials, it acknowledges that "80% of the dirt and grime that enters your building is tracked in on the shoes of employees and visitors." UniFirst knows that any contract for services or products entered into with any company such as NECC or Ameridose has a direct benefit for customers, who are the intended beneficiaries of such contracts. For example, UniFirst has stated on its website and in marketing materials that over 70% of customers say that a poorly maintained facility "is enough reason not to patronize a business again," and that by hiring UniFirst, a company's "business image will remain spotless, and your customers and employees will know you care."
- 169. UniFirst markets its products and services aggressively, and represents that, among other things, "Itlo help with your infection control offorts, UniFirst delivers

fresh mops and wipers and picks up your soiled ones on a regular schedule. We maintain inventory, perform hygienic laundering, and replace any worn out items."

- 170. UniFirst entered into a Contamination Control Service Agreement ("CCSA") with NECC on October 7, 2008, and renewed it thereafter, such that a contract existed in calendar years 2011 and 2012.
- 171. According to the terms of the CCSA and later iterations, UniFirst agreed to furnish services with supporting materials necessary for the performance of its duties, which expressly included cleaning each Cleanroom at the NECC facilities. UniFirst's duties were outlined in a Service Schedule attached and incorporated into the CCSA first signed and thereafter in force and effect. UniFirst's duties included cleaning and sanitizing each anteroom and cleanroom. The areas to be cleaned and sanitized by UniFirst employees included but were not limited to the floors, ceilings, and hoods of each room. UniFirst agreed to a triple decontamination process for each room, using products provided by UniFirst.
- 172. Unifirst agreed that, among other things, it would specifically provide its staff with cleanroom training and training regarding NECC's Standard Operating Procedures.
- 173. UniFirst performed services and sold products to NECC each month, from calendar year 2010 through September 2012, and UniFirst invoiced NECC for services rendered.
- 174. During the stated time frame, UniFirst failed to meets its own written standards in performing its contractual duties, allowing the contamination of the clearrooms UniFirst was entrusted to clean in the following ways: (A) UniFirst

employees, contractors and/or representatives, including those within the UniClean division, entered the NECC facilities (including the anterooms) in street clothes, without donning sterile or contaminant-free such as shoe covers, hair caps, coveralls, and gloves that were readily available at the NECC facilities; (B) UniFirst employees, contractors and/or representatives brought into the NECC anterooms and cleanrooms cleaning equipment, including mops, mop heads, sponges and buckets that had been moved through exterior environments, even though such equipment had not been sanitized by or cleaned appropriately, allowing contamination to occur throughout various parts of the NECC facility; and (C) UniFirst employees, contractors and/or representatives failed to clean or wipe shoes, boots and other footwear on floor mats used in the room entry process, thereby allowing contaminants into and throughout the NECC facility.

- 175. UniFirst had actual knowledge of the dangers of bacteria, mold and other microorganisms. UniFirst knew or should have known that such contaminants if not eliminated would expose patients and end use consumers such as each stated Plaintiff, to contamination of products produced by NECC in its cleanrooms.
- 176. UniFirst had actual knowledge of the very mold that was ultimately found in count five NECC facility. In a "white paper" found on the www.unifirst.com website, UniFirst identifies aspergillus niger as a "mold" that grows when garments are contaminated. In the white paper UniFirst acknowledges that this mold represents one of the most common types of microorganism contaminants found in facilities like the NECC location.
- 177. Aspergillus niger was found or brought into in the NECC facility.
  UniFirst failed to perform the job it was hired to do.

178. As a result of failures and omissions, UniFirst (solely or in concert with NECC) negligently allowed contaminants such as *aspergillus* into every cleanroom where recalled products were made, composed, mixed, prepared, packaged and stored.

179. UniFirst, its agents, and employees knew or should have known of the dangers of allowing contaminants into the NECC facility, including its anterooms and cleanrooms. UniFirst did not conduct appropriate due diligence to follow its own policies and procedures, and failed to follow NECC policies and procedures when in that facility.

## PERTINENT MASSACHUSETTS LAW

180. In order to purchase compounded drugs from NECC, it was necessary for both NECC and the Health Care Providers to comply with Massachusetts state law, which governed the compounding and dispensing activities of NECC according to Massachusetts law where and when, as here, a Massachusetts pharmacy is asked to fill

and dispense a controlled substance prescribed by an out-of-state licensed prescriber.

181. Massachusetts law does not permit the practice of ordering and dispensing compounded drugs for office use, requiring instead an individual prescription for a specific named patient. Massachusetts General Law Chapter 94C and Department of Public Health regulations (105 CMR 721.000) require that pharmacies and pharmacists dispense medications pursuant to a valid prescription from an authorized practitioner for a specific patient. This prescription must be valid as defined under Massachusetts statutes and regulations, not under the rules governing prescriptions in the recipient state." These

<sup>&</sup>lt;sup>1</sup> The Commonwealth of Massachusetts Executive Office of Health and Human Services, Department of Public Health, Division of Health Professionals Licensure, Board of Registration in Pharmacy, Advisory: Compounding Pharmacies and Pharmacists (October 2012), http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy-alert-compounding.pdf.

laws provide that that writing prescriptions for the "general dispensing to patients" is forbidden; that the name of a particular patient and prescribing doctor appear on the prescription; and regulations require that the name and address of a particular patient be present on a prescription's label. Massachusetts prescription dispensing policy thereby maintains the traditional physician-pharmacist-patient relationship, thereby greatly increasing the likelihood that compounded drugs will be used in a timely and safe manner.

- 182. The Massachusetts analog to New Jersey's Consumer Fraud Act
  ("NJCFA") is Mass. Gen. Laws Ann. Ch. 93A et seq. ("Chapter 93A") Chapter 93A
  also prohibits false representations deceptive acts and practices and makes violations of
  statutes, regulations and guidelines intended to protect consumers safety a per se
- violation of the Act, giving rise to a private cause of action for damages, multiple damages, fees and costs.
  - 183. New Jersey's CFA and Massachusetts' Chapter 93A are not mutually exclusive laws and both Acts constitutionally and textually may and should apply at the same time to the misconduct of a party herein because both State's laws prohibit and proscribe the misconduct and both State's under dual sovereignty principles have an independent right to apply its law and provide remedy where applicable.

### V. SUBSTANTIVE COUNTS

A. SUBSTANTIVE COUNTS AGAINST THE NECC RELATED DEFENDANTS, ARL, LIBERTY and UNIFIRST

COUNT I - NEGLIGENCE UNDER MASSACHUSETTS OR OTHER APPLICABLE STATE LAW

<sup>&</sup>lt;sup>2</sup> Mass. Gen. Laws Ann. ch. 94C, § 19.

<sup>&</sup>lt;sup>3</sup> Mass. Gen. Laws Ann. ch. 94C, § 22.

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184. Plaintiffs incorporate by reference all proceeding paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

185. As the designer, tester, compounder, seller, marketer, supplier, and/or distributor of consumer products, the ARL and NECC Related Defendants, Ameridose, ARL, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin, owed a duty to each stated Plaintiff to comply with existing standards of care, and to exercise due care, in providing a safe and quality product to each stated Plaintiff.

## 186. Specifically, but without limitation:

a. Ameridose, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin owed every single identified Plaintiff and their physicians a duty to compound, and provide methylprenisolone acetate that was safe and free of contamination.

b. Ameridose, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin owed each Plaintiff and their physicians a duty to provide reasonable and correct warnings, instructions and labeling to each Plaintiff or his/her physicians.

c. Ameridose, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin owed each Plaintiff and their physicians a duty to properly store and ship methylprenisolone acetate.

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d. ARL owed each Plaintiff duties to properly conduct tests to insure that the NECC methylprenisolone acetate was sterile, safe and free of contamination, and to not authorize and prevent its reports from being used in the marketing of products that were not fully tested where and when it knew or had reason to know that was occurring.

- 187. The NECC-Related Defendants breached these respective duties and were otherwise negligent in their design, compounding, formulation, making, creation, sale, testing, marketing and distribution of the recalled MPA steroid medication, which was administered to each named Plaintiff. These Defendants failed to exercise due care in accordance with the standard of care and skill required of, and ordinarily exercised by, a designer, compounder, formulator, maker, creator, tester, seller, marketer and distributor
- of sterile preparations and medications, as licensed to do so by the Commonwealth of Massachusetts.
  - 188. The NECC-Related Defendants, by and through their supervisors, staff and agents engaged in designing, compounding, formulation, making, creation, sales, testing, marketing and distributing the recalled MPA in a negligent manner.
  - 189. The NECC-Related Defendants further breached their respective duties of care by failing to store, hold and compound the components of the recalled medications; by failing to properly design, compound, formulate, create, make, test, sell and/or distribute MPA so that it would not be contaminated with a fungus; by failing to properly maintain facilities where sterile medications were compounded, packaged or stored in a clean, sanitary manner, or taking reasonable steps and measures to assure these functions were performed in clean, sanitary and sterile facilities; by failing to oversee the security

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and quality control of NECC's or their compounding and distribution facilities; and/or by allowing contaminated and unsafe medications compounded to reach the stream of commerce for use by each Plaintiff.

- 190. Ameridose, ARL, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin breached the duties owed to Plaintiff by failing to use reasonable care in designing, compounding, formulating, making, creating, testing, marketing, distributing and/or selling preservative free MPA.
- 191. NECC has been declared insolvent by the Bankruptcy Court presiding over its Bankruptcy Petition and prosecution of any and all actions against it are stayed.
- 192. In addition to violating the laws of Massachusetts where NECC was headquartered and maintained its facility for compounding, packaging, storing and distributing contaminated and adulterated drugs which were then shipped and distributed to New Jersey for administration to patients, including each named Plaintiff, all or some of the NECC-Related Defendants also violated the New Jersey Product Liability Act.
  - 193. The negligence of Ameridose, ARL, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin was a proximate cause of each Plaintiffs' injuries, causing harm and losses to each.
  - 194. As a direct and proximate cause of ARL and the NECC Related Defendants' joint and several acts of negligence, carelessness and recklessness, each Plaintiff was exposed to fungal contaminated steroid medication on the stated dates.
  - 195. As a direct and proximate result of negligence of Defendants identified in this Count, each Plaintiff was injected as alleged with at least one contaminated dose of

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methylprednisolone acetate and consequently suffered injuries, conscious pain and suffering, emotional distress, and economic losses as described above.

WHEREFORE, the Plaintiffs each demand judgment against Defendants, jointly and severally, and in the alternative for damages and costs of suit.

## COUNT II - NEGLIGENCE PER SE

- 196. Plaintiffs incorporate by reference all proceeding paragraphs in this Complaint as if fully set forth herein at length, and further alleges:
- 197. Ameridose, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin owed Plaintiff a duty under Massachusetts law to maintain the premises of the NECC pharmacy "in a clean and sanitary manner[,]" 247 CMR 6.02(1), and free from contamination.
  - 198. Ameridose, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin breached the duties owed to Plaintiff by failing to use reasonable care in maintaining the premises of the pharmacy "in a clean and sanitary manner[,]" 247 CMR 6.02(1), and free from contamination.
  - 199. As a direct and proximate cause of the defendants Ameridose, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin's negligence, carelessness and recklessness in violating these statutory imposed duties, each Plaintiff was exposed to fungal contaminated steroid medication as alleged.
  - 200. As a direct and proximate result of negligence of the defendants identified in this Count, each Plaintiff was injected with a contaminated dose of methylprednisolone

acetate and consequently suffered injuries, conscious pain and suffering, emotional distress, and economic losses as described above.

WHEREFORE, the Plaintiffs demand judgment against Defendants, jointly and severally, and in the alternative for damages and costs of suit.

#### COUNT III - NEGLIGENT SUPERVISION

- 201. Plaintiffs incorporate by reference all proceeding paragraphs in this Complaint as if fully set forth herein at length, and further allege:
- 202. ARL, and the NECC Related Defendants each respectively had an obligation and duty to exercise due care, and comply with the then existing standard of care to investigate and hire professional and competent employees to create; test, package, market and/or distribute the compounded medications and to make sure the compounded drugs being made, tested, packaged and stored did not create any harm or risk to each Plaintiff and others who received the compounded medications.
  - 203. Defendants Ameridose, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin each also respectively had an obligation and duty to exercise due care and comply with the then existing standard of care to investigate and hire professional and competent employees or vendors to maintain NECC's production, packaging and storage facility and make sure the purported compounded sterile drugs did not create any harm or risk to Plaintiff and others who received NECC's compounded medications.
  - 204. In breach of these duties, ARL and the NECC Related Defendants failed to exercise due care and failed to supervise their respective employee(s), agent(s) or

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vendor(s), who were at all times working within the scope of their employment and authority. Specifically, and without limitation:

a. All or some of these Defendants' employee(s), agent(s) or vendor(s) failed to properly test the steroid medication and these Defendants were negligent in monitoring and supervision of their employee(s), agent(s) or vendor(s) regarding this important task and function;

b. All or some of these Defendants' employee(s), agent(s) or vendor(s) failed to properly compound, sterilize, package, label, store and dispense the steroid medication and these Defendants were negligent in monitoring and supervision of their employee(s), agent(s) or vendor(s) regarding these important tasks and functions; and/or

c. All or some of these Defendants' employee(s), agent(s) or vendor(s) failed to properly review prescriptions for NECC's compounded medications for compliance with applicable prescription laws and/or gave incorrect information or instructions on requisite prescription requirements, and these Defendants were negligent in monitoring and supervision of their employee(s), agent(s) or vendor(s) regarding these important tasks and functions.

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d. All or some of these Defendants' employee(s), agent(s) or vendor(s) failed to properly instruct, warn or advise as to the storage, handling and preadministration administration inspection of NECC's preservative free sterile compounded and/or gave incorrect information or instructions or warnings, and these Defendants were negligent in monitoring and supervision of their

employee(s), agent(s) or vendor(s) regarding these important tasks and functions

- e. These Defendants were otherwise negligent in hiring, training, and supervising their employees, agents or vendors relevant to this matter.
- 205. ARL and the NECC-Related Defendants knew, or should have known, that their respective employee or agent did not follow proper procedures and precautions and knew or should have known of the risks created by failing to do so.
- 206. As a direct and proximate cause of these breaches of duty ARL's and the NECC- Related Defendants permitted the subject MPA steroid lots to become contaminated and distributed to patients throughout the United States, including each Plaintiff.
- 207. As a direct and proximate cause of ARL's and the NECC Related respective negligence, carelessness and recklessness, each Plaintiff was exposed to fungal contaminated steroid medication on the stated dates.
- 208. As a direct and proximate result of negligence of the defendants identified in this Count, each Plaintiff was injected with a contaminated dose of methylprednisolone acetate and consequently suffered injuries, conscious pain and suffering, emotional distress, and economic losses as described above.

WHEREFORE, each Plaintiff demands judgment against Defendants, jointly and severally, and in the alternative for damages and costs of suit.

COUNT IV - STRICT PRODUCTS LIABILITY: DEFECTIVE
MANUFACTURING LIABILITY UNDER NEW JERSEY PRODUCTS
LIABILITY ACT

209. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

- 210. Defendants Ameridose, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and/or Glenn Chin is or are a manufacturer, designer, maker, formulator, distributor, seller, and/or supplier of the NECC MPA sold told to and administered to each Plaintiff.
- 211. The subject MPA was manufactured, compounded, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants Ameridose, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and/or Glenn Chin.
- 212. The NECC MPA was defective in its manufacture and deviated in a material way from its formulation, design specifications and/or performance standards, including but to limited to USP guidelines and requirements, such that it was contaminated with fungi and other toxic or infectious microorganisms, all through no fault of any Plaintiff.

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- 213. The NECC MPA was defective in its manufacture and deviated in a material way from the design specifications and/or performance standards and consequently caused a national outbreak of fungal meningitis and other serious fungal infection related disorders that are serious, long lasting, permanent or fatal, and difficult to diagnose and treat.
- 214. NECC preservative free MPA was sold without proper and adequate warnings and labelling.

215. As a direct and proximate cause of the defective condition of the NECC MPA administered to each stated Plaintiff, each was exposed to a fungus contaminated preservative free steroid medication during steroid injection procedures.

- 216. As a direct and proximate result of negligence of the defendants identified in this Count, each Plaintiff was injected with one or more contaminated doses of methylprednisolone acetate and consequently suffered injuries, conscious pain and suffering, emotional distress, and economic losses as described above.
- 217. Defendants Ameridose, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and/or Glenn Chin are liable to Plaintiff under the New Jersey Products Liability Act and/or equivalent Massachusetts products liability laws.
- 218. Defendant's actions and omissions as alleged in her Complaint constitute a flagrant disregard for human life and safety, malice, and aggravated and egregious fraud, so as to warrant the imposition of punitive damages.

WHEREFORE, each Plaintiff demands judgment against Defendants, jointly and severally, and in the alternative for damages and costs of suit.

## COUNT V - NEGLIGENCE AND GROSS NEGLIGENCE (Against Liberty)

- 206. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:
- 207. Liberty owed each Plaintiff a duty to exercise reasonable care and to follow all applicable laws and standards during the manufacture, construction, installation, design, certification, and ongoing maintenance of the clean rooms in order to prevent or eliminate contamination of the clean rooms.

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- 208. Liberty failed to exercise reasonable care in one or more of the following ways, so far as is presently known:
  - a. by failing to properly design and install the 2006 and 2008 Cleanroom
     ceiling grids, ceiling panels, light fixtures, and HEPA filtration modules;
  - b. by failing to properly design and install the 2006 and 2008 Cleanroom fire suppression system;
  - c. by failing to use proper materials in the construction of the ceiling of the Cleanrooms;
  - d. by failing to properly survey existing Cleanrooms and the facility as a
    whole to properly assess the risks associated with construction of
    subsequent Cleanrooms;
  - e. by failing to install a hard cap/hard ceiling over the ceiling of each Cleanroom to protect from contamination, despite Liberty's actual and/or constructive knowledge that the areas between the ceilings of the 2006 and 2008 Cleanrooms were prone to excessive contamination and water damage;
  - f. by prematurely certifying the 2006 and 2008 Cleanrooms;
  - g. by disrupting or otherwise breaching the cleanliness of the Cleanrooms
    through the installation of faulty ceiling grids, improper materials, and the
    conduct of subsequent work to each Cleanroom, resulting in or
    contributing to their contamination;
  - h. by failing to take reasonable steps to properly certify the Cleanrooms to ensure their cleanliness as required for their anticipated use;

- i. by committing other violations as shall be revealed in discovery.
- 209. Each named Plaintiff was a foreseeable victim of Liberty's negligence. Liberty knew that NECC and Ameridose were compounding drugs at their facility for national distribution and for use in patients such as Plaintiffs.
- 210. Liberty's wrongful conduct and negligence resulted in each identified Plaintiff's suffering physical injuries and economic losses.
- 211. Liberty's conduct set out above constitutes gross negligence and a reckless disregard for human life and safety, thus warranting the imposition of punitive damages.

WHEREFORE, each Plaintiff demands judgment against Defendants, jointly and severally, and in the alternative for damages and costs of suit.

## COUNT VI – NEGLIGENCE AND GROSS NEGLIGENCE (Against UniFirst)

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- 212. Each Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:.
- 213. UniFirst owed each Plaintiff a duty to exercise reasonable care to follow all applicable laws and standards, as well as NECC standard procedures, during the ongoing and regular maintenance and cleaning of the Cleanrooms in order to prevent or eliminate contamination of the Cleanrooms.
- 214. UniFirst knew or should have known that products produced, sold, and shipped by NECC required a sterile environment, and that such products would be used by end consumers such as Plaintiffs. UniFirst knew that end consumers of NECC products were the intended beneficiaries of the services to be rendered by UniFirst to NECC. UniFirst's knew that customers of a business like NECC expect and rely upon a

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clean and a safe environment for the production of goods. UniFirst knew this for nearly four years before the recall of the NECC Contaminated Drugs.

- 215. UniFirst failed to exercise reasonable care in one or more of the following ways, so far as is presently known:
  - a) UniFirst employees, contractors and/or representatives, including those within the UniClean division, entered the Cleanrooms (including the anterooms) in street clothes, without donning sterile or contaminant-free clothing such as shoc covers, hair caps, coveralls, and gloves that were readily available at the NECC facilities, thereby failing to follow its own standards and policies;
  - b) UniFirst employees, contractors and/or representatives brought into the NECC anterooms and Cleanrooms cleaning equipment, including mops, mop heads, spongers, and buckets that had been moved through exterior environments, even though such equipment had not been sanitized or cleaned appropriately, allowing contamination to occur throughout various parts of the NECC facility, such actions failing to meet UniFirst's own standards as well as recognized industry standards;
    - c) UniFirst employees, contractors and/or representatives failed to clean or wipe footwear on mats used in the cleanroom entry process, thereby allowing contaminants into and throughout the Cleanrooms; and
    - d) UniFirst employees, agents, contractors and/or representatives were negligently supervised, and failed to adhere to and follow NECC standard operating procedures.

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- 216. Each Plaintiff was a foreseeable victim of UniFirst's negligence. UniFirst knew that the NECC-Related Parties were compounding drugs at their facility for national distribution and for use in patients such as Plaintiffs.
- 217. The wrongful conduct and negligence of UniFirst resulted in each Plaintiff's suffering serious physical injuries, and distress.
- 218. As a direct and proximate result of UniFirst's negligence, as well as that of UniFirst's employees, agents, independent contractors, businesses, or others associated with and/or providing services, each Plaintiff is entitled to recover all allowable elements of damage from UniFirst for her injuries and losses.
- 219. UniFirst's conduct set out above constitutes gross negligence and a reckless disregard for human life and safety, thus warranting the imposition of punitive damages.
  - WHEREFORE, each Plaintiff demands judgment against Defendants, jointly and severally, and in the alternative for damages and costs of suit.

## B. SUBSTANTIVE COUNTS AGAINST HEALTH CARE PROVIDERS COUNT VII – HEALTH CARE PROVIDER'S NEGLIGENCE

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- 220. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:
- 221. The Health Care Providers had a duty to exercise reasonable care to ensure that the drugs they purchased in order to sell and administer to their patients, including each Plaintiff, were purchased from drug companies that complied with the laws regarding pharmaceuticals.

222. The Health Care Providers had a duty to exercise reasonable care to ensure that the drugs they provided to their patients, including the stated Plaintiffs, were purchased from a company that made safe and effective drugs.

- 223. The Health Care Providers had a duty to exercise reasonable care to ensure that the drugs they provided to their patients, including the stated Plaintiffs, were purchased from a company that utilized proper quality control, safety, and sterility measures in order to minimize the possibility that the drugs would become adulterated or contaminated.
- 224. The Health Care Providers had a duty to exercise reasonable care to avoid administering contaminated drugs, or drugs they knew or should have known to be contaminated, to each identified Plaintiff.
- 225. The Health Care Providers had a duty to provide each Plaintiff with reasonable care and treatment.
- 226. The Health Care Providers as part of their duties as to each Plaintiff's learned intermediary had a duty to obtain informed consent from every single Plaintiff for the procedure performed in the course of which adequately and accurately describing to each Plaintiff the nature of the procedure, as well as the risks of such procedure, including pertinent information regarding the drugs that were to be administered during such procedure.
- 227. In this case, where the drug came from an unaccredited, mass producing, out-of-state compounding pharmacy that was neither inspected nor regulated by the FDA, the Health Care Providers had a duty to inform each Plaintiff of the nature and source of the drug and the dangers associated therewith.

- The Health Care Providers, through their actual and/or apparent agents, servants, and/or employees breached the above-described duties of care, thereby deviating from the applicable standards of care, and were otherwise negligent, careless, and reckless in that among other things:
  - a. the Health Care Providers failed to exercise reasonable and prudent care to ensure that the drugs they purchased and provided at charge to Plaintiff were made by NECC in compliance with all applicable pharmaceutical laws;
  - b. the Health Care Providers failed to exercise reasonable and prudent care to ensure that the drug they purchased and provided to each Plaintiff were acquired from a reputable and able source and supply in compliance with all applicable pharmaceutical laws;
  - c. the Health Care Providers failed to know and understand the source and supply of the drug they provided to each Plaintiff;
  - d. the Health Care Providers failed to use appropriate, necessary and reasonable due diligence and investigatory steps and measures necessary to vet, evaluate and determine the safety and quality of NECC's drugs, and in particular; determine if NECC could properly and suitably compound, package and provide sterile preservative-free drugs for administration to each Plaintiff;
  - e. the Health Care Providers failed to follow the reasonable ASHP Guidelines on Outsourcing Sterile Compounding Services, which had they followed, would have established that NECC's products were unsafe or unsuitable for administration to each Plaintiff;
  - f. the Health Care Providers failed to exercise reasonable and prudent care to ensure that the drug they provided to each Plaintiff was produced in sanitary, sterile conditions;
  - g. the Health Care Providers failed to properly inform their patients (the identified Plaintiffs) that the drug(s) administered had compounded and not manufactured at a facility approved by the FDA;
  - h. the Health Care Providers failed to properly inform any Plaintiff of the risks and dangers associated with the administration of the drug; and they failed to inform her that they had obtained the drug via mail order from NECC, a mass-producing, unaccredited, non-FDA regulated compounding pharmacy;

- i. the Health Care Providers failed to exercise reasonable care to avoid administering to each Plaintiff an adulterated, contaminated and unreasonably dangerous drug;
- i. the Health Care Providers failed to conduct adequate due diligence regarding whether NECC was a reputable and safe supplier of sterile injectable compounds;
- k. the Health Care Providers failed to visit NECC's facilities before procuring compounded drugs from NECC;
- the Health Care Providers failed to investigate and exercise sufficient due diligence before administering drugs procured from NECC, including failing to investigate or inquire concerning NECC's compounding practices, standard operating procedures, pharmacist training, and risk management protocols;
- m. the Health Care Providers failed to determine whether NECC had a history of recalling compounded medications before procuring medicines from that company;
- n. the Health Care Providers failed to investigate NECC's regulatory history with the FDA and/or the Massachusetts Board of Registration in Pharmacy before procuring drugs from NECC;
- the Health Care Providers failed to determine whether NECC had a history of product liability suits before procuring medicines from that company;
- the Health Care Providers failed to determine whether NECC was accredited by any legitimate accreditation organization suits before procuring medicines from that company;
- q. 'the Health Care Providers failed to keep abreast of the dangers of sterile compounding;
- r. the Health Care Providers purchased compounded drugs in bulk from NECC without using patient specific individual prescriptions in contravention of law;
- s. It is believed the Health Care Providers failed to appropriately store drugs purchased from NECC to reduce the risk of the growth of contaminants;
- t. the Health Care Providers failed to adequately supervise and train the physicians, nurses, agents and employees who ordered drugs from NECC;

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- u. the Health Care Providers failed to implement policies and procedures that would prevent the procurement of purportedly sterile drugs from an out-of-state compounding pharmacy with a deplorable facility and sterility procedures, a checkered regulatory past, product recall problems, and a history of product liability suits;
- v. the Health Care Providers administered drugs to any Plaintiff without taking reasonable steps to ensure that those medicines were from a reputable supplier and were not contaminated with lethal pathogens;
- w. the Health Care Providers failed to promptly notify any of the identified Plaintiffs that each was injected with potentially contaminated steroids and failed to recommend that she receive prompt treatment of her potential infections and other symptoms;
- x. the Health Care Providers selected and administered a preservative free version of MPS steroid medication where and when versions with preservatives were available and or there were manufactured preservative free therapeutic substitutes available;
- y. the health care providers dispensed a medication not prescribed and dispensed by the compounding pharmacy for Plaintiff, but rather a compounded medication prescribed and dispensed by NECC for anther purported patient; and
- z. the Health Care Providers failed to exercise reasonable care in such other manners as may be shown through discovery and at trial.
- 229. The physicians, nurses, agents, employees and representatives who decided to procure drugs from NECC and who administered them to each Plaintiff were employees or agents of the respective Health Care Providers, and they were acting within the course and scope of their employment or agency. Accordingly, the Health Care Providers are liable for the consequences of said person's or persons' conduct pursuant to the doctrine of respondent superior.
- 230. As a direct and proximate result of the negligence of Health Care

  Providers, each Plaintiff was administered one or more contaminated steroid injection
  which caused him to sustain injury and economic losses.

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- 231. The actions of the Health Care Providers did not meet even the most minimal diligence to ensure that they were not injecting contaminated, adulterated, tainted, and unreasonably dangerous drugs directly into the bodies of their patients, including each Plaintiff.
- 232. The acts and omissions of the Health Care Providers constituted such utter disregard for the rights of others, and such utter disregard for prudence, that they amount to complete neglect of the safety of patients, including every stated Plaintiff.
- At all times material hereto, Health Care Providers purchased, stored, handled, sold, used, administered, and/overall possessed and utilized contaminated MPA with willful and intentional disregard to the individual rights of Plaintiff, warranting an award of punitive damages to each Plaintiff.
- 234. The Health Caro Providers represented that Plaintiff received FDA-approved Depo-Medrol when in fact they injected Plaintiff with NECC's compounded MPA.
- 235. Health Care Providers thereby acted with oppression, fraud and malice toward each Plaintiff, therefore, each requests additional damages for the sake of example and for the purpose of punishing Health Care Providers for their conduct, in amounts sufficiently large to be an example to others, and to deter these Health Care Providers and others from engaging in similar conduct in the future.
- 236. The above described acts and omissions on the part of the Health Care
  Providers were reckless and intentional. Health Care Providers were aware of, but
  consciously disregarded, a substantial and unjustifiable risk of such a nature that their
  disregard constitutes a gross deviation from the standard of care that an ordinary person

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would exercise under all the circumstances. Claimants therefore are entitled to an award of punitive damages against the Health Care Providers.

WHEREFORE, each Plaintiff demands judgment against Defendants, jointly and severally, and in the alternative for damages and costs of suit.

## COUNT VIH -LACK OF INFORMED CONSENT CLAIM AGAINST HEALTH CARE PROVIDERS

- 237. Each Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:
- 238. It is alleged that each Plaintiff was not afforded appropriate informed consent with respect to the risk of the procedure.
- 239. The Health Care Providers provided high risk and unreasonably dangerous contaminated NECC compounded drugs to patients, including Plaintiff, in the place of safe, medically acceptable drugs.
- 240. The Health Care Providers failed to inform their patients at Surgical Center, including each Plaintiff, that they were being administered an unsafe, unreasonably dangerous drug compounded by NECC rather than a high quality drug produced by an FDA regulated manufacturer.
- 241. Many, if not all, of the Health Care Providers prepared a Consent for Treatment form. The form, which was presented to each Plaintiff by the Health Care Providers, and which each Plaintiff read and relied upon when agreeing to accept treatment, failed to inform each Plaintiff of the risks and benefits of the procedures before it was performed. When presenting the form to each Plaintiff, the Health Care Providers knew that nobody on its behalf would be informing each Plaintiff of the inferior, far more risky and unreasonably dangerous nature of the NECC drug that would

be administered to each Plaintiff. Health Care Providers knew that if any of the stated Plaintiffs was informed of the true nature of the NECC drugs, Plaintiff would decline treatment with NECC compounded drugs, threatening the Health Care Providers' profits.

As a proximate result of the Health Care Providers' wrongful conduct, each Plaintiff underwent the procedure which used NECC's contaminated preservative free MPA and suffered gricvous bodily injury, required medical treatment, incurred substantial medical bills, suffered severe mental anguish.

WHEREFORE, each stated Plaintiff demands judgment against Defendants, jointly and severally, and in the alternative for damages and costs of suit.

#### COUNT IX -BATTERY CLAIM AGAINST HEALTH CARE PROVIDERS

- 243. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:
- 244. As part of the medical treatment each Plaintiff received at the Health Care Providers' facility, their agents and/or employees purchased, prescribed and administered, via injection into each Plaintiff's body, NECC drugs which were not sterile and which contained substances, including fungal or bacterial contamination, harmful to human life. Each Plaintiff, however, was unaware of the substantial health and safety risk inherent in the use of NECC drugs, that the drugs contained harmful fungus and other adulterants and did not consent to the injection of contaminated drugs into each Plaintiff's body.
- 245. As a direct and proximate result of Health Care Providers wrongful acts set forth herein, each Plaintiff was injected by Health Care Providers with NECC

contaminated drugs, intentionally inflicting and causing a harmful and offensive contact with each and every Plaintiff.

246. As a direct and proximate result of this unwanted offensive and harmful contact, each Plaintiff suffered bodily injury and mental anguish.

WHEREFORE, the named Plaintiffs demand individual judgments against

Defendants, jointly and severally, and in the alternative for damages and costs of suit.

### COUNT XI: VIOLATION OF NEW JERSEY AND MASSACHUSETTS STATE CONSUMER PROTECTION STATUTES

- 257. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:
- . 258. The NECC Related Defendants and Health Care Providers engaged in trade and commerce within the State of New Jersey and the Commonwealth of Massachusetts.
  - 259. The NECC Related Defendants and Health Care Providers have a statutory duty to refrain from unfair or deceptive acts or trade practices in the promotion and sale of the NECC contaminated drugs.
  - As described herein, the Health Care Providers' submitted to NECC fictional or past patient named in order to obtain office supplies of preservative free MPA drugs from NECC in violation of Massachusetts' controlled substances and pharmacy laws and regulations. Such submissions constitute actionable violations of New Jersey's and Massachusetts' respective consumer protection statutes.
  - 261. As alleged, the NECC Related Defendants and Health Care Providers represented that the medication being administered had characteristics, uses and benefits that they did not have.

- 262. As alleged herein, the NECC Related Defendants and Health Care Providers represented that their 'products were of a particular standard, origin, manufacturer, quality and grade that they either knew or should have known was not of the standard, origin, manufacturer, quality or grade described.
- 263. The NECC-Related Defendants and Health Care Providers failed to provide accurate disclosures of all material information before each stated Plaintiff agreed to be injected with an NECC contaminated drug.
- 264. The Health Care Providers represented to their patients and their medical benefits providers that they were being administered or had been administered FDA-approved Depo-Medrol when in fact they injected patients, including each stated Plaintiff, with NECC's compounded MPA.
- 265. The NECC-Related Defendants and Health Care Providers willfully and knowingly failed to abide by regulations, laws and guidelines set forth to protect consumer safety, constituting a violation of the consumer protection statutes set forth herein.
  - 266. The conduct and omission of the Health Care Providers, NECC, Ameridose's, MSM/MSMSW's, Gregory Conigliaro's, Douglas Conigliaro's, Carla Conigliaro's, Barry Cadden's, Lisa Cadden's, Glenn Chin's and/or ARLs', constituted unfair and deceptive acts and practices under New Jersey and Massachusetts unfair and deceptive acts and practices laws, including, but not limited to all or some of the following:
    - a. Misrepresenting the nature, quality, and characteristics about NECC's compounded MPA;

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- b. Unfairly violating regulations, laws and guidelines set forth to protect consumer safety and the dispensing of pharmaceutical products;
- c. Unfairly exposing unknowing consumers, including each stated Plaintiff, to significant, unnecessary risk of harm and actual harm and injury; and
- d. All other unfair, fraudulent and deceptive acts set forth herein
- 267. The NECC Related Parties and Health Care Providers acts and omission alleged herein aided and abetted the wrongful and tortious conduct and activities of each, and/or served to further the conspiracy alleged herein that the NECC Related Parties, ARL and the Health Care Providers were parties to, while at the same time, and under false pretenses, allowed the Health Care Providers to obtaining money from each stated. Plaintiff and/or their medical care benefit providers for NECC's contaminated drugs that would not have been paid had the Health Care Providers not engaged in unfair and deceptive conduct.
  - 268. Had the NECC Related Parties, ARL and the Health Care Providers not engaged in the deceptive conduct described above, none of the stated Plaintiffs would not have purchased and/or paid for NECC's contaminated MPA.
  - 269. The Health Care Providers' acts omissions, and civil conspiracy alleged herein constitute unfair competition, unfair or deceptive acts or practices, and/or false representations in violation of New Jersey's and Massachusetts' respective consumer protection statutes, which statutes are not mutually exclusive and under the doctrine of Dual Sovereignty may each apply.

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- 270. The Health Care Providers' willful and knowing withholding of important safety information and critical product information constitutes a violation of New Jersey's and Massachusetts' consumer protection statutes set forth herein.
- The NECC Related Parties, ARL and the Health Care Providers actively, knowingly, and deceptively concealed the MPA product's dangerous properties and life-threatening risks of which they knew or should have known. This conduct evidences bad faith and unfair and deceptive practices.
- 272. The NECC Related Parties, ARL and the Health Care Providers engaged in conduct as described herein that created a likelihood of confusion and misunderstanding.
- 273. The practices described herein are unfair because they offend public policy as established by statutes, the common law, or otherwise. Additionally the Health Care Providers were unethical and unscrupulous, and caused substantial injury to consumers. The Health Care Providers engaged in unconscionable actions and courses of action.
- 274. The NECC Related Parties', ARL's and the Health Care Providers' willfully engaged in the conduct described herein, which they knew was deceptive, in the course of business, trade and commerce, and had a deleterious impact on the public interest.
- 275. The NECC Related Parties, ARL and the Health Care Providers are liable to each Plaintiff for all statutory, direct and consequential damages, and fees and costs resulting from this breach, including multiple damages.

276. Each Plaintiff was injected with NECC Contaminated Drugs for personal use and thereby suffered ascertainable losses as a result of the Health Care Providers' actions in violation of the consumer protection laws.

- 277. The NECC Related Parties', ARL's and the Health Care Providers actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of the following state consumer protection statutes, as listed below.
  - Mass. Gen. Laws Ann. Ch. 93A et seq.;
  - New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 et seq.
- The NECC Related Parties, ARL and the Health Care Providers violated the statutes that were enacted in New Jersey and Massachusetts to protect consumers tagainst unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the NECC MPA drug was fit to be used for the purpose for which it was intended, when, in fact, it was defective and dangerous, and by other acts alleged herein.
- 279. The actions and omissions of the NECC Related Parties, ARL and the Health Care Providers alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.
- 280. Each Plaintiff relied upon the NECC Related Parties', ARL's and the Health Care Providers' misrepresentations and omissions in determining which product to be administered to her.

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- 281. By reason of the unlawful acts engaged in by the NECC Related Parties, ARL and the Health Care Providers, and as a direct and proximate result thereof, each Plaintiff has suffered ascertainable losses and damages.
- As a direct and proximate result of the NECC Related Parties', ARL's and the Health Care Providers' violations of the states' consumer protection laws, each Plaintiff sustained an ascertainable loss and other damages and are entitled to statutory and compensatory, damages in an amount to be proven at trial.
- 283. Pre-suit notice of this claim is not required. The NECC Related Parties in the NECC MDL proceedings, In Re New England Compounding Pharmacy, Inc. Products Liability Litigation, MDL No. 2419, Dkt. No. 1:13-md-2419 (FDS) (D. Mass)), have agreed to waive pre-suit notice requirements, including MGL c. 93A's pre-suit demand requirement. The waiver is documented in Case Management Order No. 6 entered in MDL No. 2419 on June 28, 2013. ARL, and the Health Care Provides do not maintain a place of business or keep assets within the Commonwealth of Massachusetts thus negating the pre-suit notice requirement under Chapter 93A.

#### COUNT XII - CONSORTIUM

#### (Against all Defendants)

- 284. Plaintiffs incorporate all relevant allegations as if set forth fully herein.
- 285. At the time of the injuries complained of by each stated Plaintiff, each Plaintiff was married (as alleged above) and each Plaintiff continues to be married (excluding Kaneshiki). Lauran Chann is the spouse of Kenneth Chann, Eldean Langley is the spouse of Joseph Langley, Helen Elwell is the spouse of Samuel Elwell, and Marilyn Hiraldo (Masonet) is the spouse of Edward Hiraldo

- 286. As a result of the wrongful and negligent acts of the Defendants, and each of them, each Plaintiff was caused to suffer, and will continue to suffer in the future, loss of consortium, loss of society, affection, assistance, and conjugal fellowship, all to the detriment of their marital relationship.
- 287. All the aforesaid injuries and damages were caused solely and proximately by the negligence of the Defendants.

WHEREFORE, each separate Plaintiff demands judgment against Defendants, jointly and severally, and in the alternative for damages and costs of suit.

#### JURY DEMAND

Each Plaintiff demands a trial by jury as to all claims in this action.

#### **DESIGNATION OF TRIAL COUNSEL**

Pursuant to R. 4:5-1(c) and R. 4:25-4, Plaintiff hereby designates JEFFREY KEISER and MARK ZAMORA as trial counsel. Mark Zamora has a pro hac motion filed.

#### **RULE 4:5-1 CERTIFICATION**

Plaintiffs certify that the matter in controversy is not the subject of any other pending or contemplated judicial or arbitration proceedings. A Multi District Litigation proceeding and a Chapter 11 Bankruptcy related to this matter is related to is identified in the body of the Complaint. Plaintiffs are not currently aware of any other parties that should be joined in this particular action. In addition, Plaintiffs recognize a continuing obligation to file and serve on all parties and the Court an amended certification if there is a change in the facts stated in this original certification.

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Respectfully submitted,

JEFFREY M. KEISER, ESQUIRE

Attorney for Plaintiffs

THE ORLANDO FIRM Co-Counsel for Plaintiffs

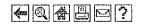
Mark Zamara

Member of the Bar of the State of Georgia

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Party Document

VENUE : ESSEX COURT : LAW CVL DOCKET # : L 007568 14

CASE TITLE : CHANN SR VS PREMIER ORTHOPAEDIC ASSOCIATES SURGICA

FILING PARTY : LANGLEY ELDEAN MULTI PARTY INDIC : Y

MULTI TARGET INDIC: Y

DOCUMENT TYPE : AFFID MERIT DOCUMENT STATUS : ACTIVE DATE FILED : 01 09 2015 IMPOUND INDICATOR: NO

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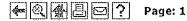
DATE ENTERED : 01 15 2015 LST MAINT DTE: 01 15 2015

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Session ID: 8YDNBM Case Count: 1
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**END OF LIST** 

VENUE : ESSEX COURT : LAW CVL DOCKET # : L 007568 CASE TITLE : CHANN SR VS PREMIER ORTHOPAEDIC ASSOCIATES SURGICA

DOCUMENT TYPE : AFFID MERIT DATE FILED : 01 09 2015

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031	JOHN DOES BUSINESS 1	-100		T	DF	ATTY	REQUIRED
030	JOHN DOES CORPORATIO	NS 1-100		Т	DF	ATTY	REQUIRED
029	JOHN DOES 1-10			T	DF	ATTY	REQUIRED
028	UNIFIRST CORPORATION			Т	DF	ATTY	REQUIRED
027	LIBERTY INDUSTRIES I	NC		Т	DF	ATTY	REQUIRED
026	ARL BIO PHARMA INC			Τ	DF	ATTY	REQUIRED
025	MEDICAL SALES MANAGE	MENT SW		T	DF	ATTY	REQUIRED

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Law Offices

### JEFFREY M. KEISER, ESQUIRE

Jeffrey M. Keiser

Certified by the Supreme Court
of New Jersey as Civil Trial Attorney
Lynn A. Godtfring, RN, JD\*
\*NJ and PA Bar

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January 28, 2015

Christopher Wolk Esquire Law Offices of Jay J. Blumberg 158 Delaware Street P O Box 68 Woodbury, NJ 08096

Re: Chann v. Premier Orthopedics, et al Docket No. ESX-L-007568-14

Dear Mr. Wolk:

I enclose copy of the filed Affidavit of Merit signed by William Matouzzi, M.D. in connection with the above matter.

I understand that the District Court has ordered that the Affidavits of Merit that have been filed by co-counsel as to the Premier defendants are deemed to be filed on behalf of all plaintiffs in that action.

I note additionally that we have served on your clients the Summons and Complaint. I have not received any acknowledgment nor has there been an Answer filed or any other action taken. Would you please advise as to the status of your reply so that we may document our file.

Thank you for your anticipated cooperation in this matter.

Very truly yours,

JEFFREY M. KEISER

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LAW OFFICE OF JEFFREY M. KEISER (Attorney ID # 014481974) 76 E. Euclid Ave. Suite 201 Haddonfield, New Jersey 08033 Attorneys for Plaintiffs

KENNETH CHANN SR., LAURA CHANN,: EMIKO KANESHIKI, JOSEPH LANGLEY,: ELDEAN LANGLEY, SAMUEL ELWELL,: HELEN ELWELL, EDWARD HIRALDO, and: MARILYN HIRALDO (MASONET) :

SUPERIOR COURT OF NEW JERSEY LAW DIVISION ESSEX COUNTY

Plaintiffs,

v.

DOCKET NO. ESX-L-007568-14

**CIVIL ACTION** 

PREMIER ORTHOPAEDIC ASSOCIATES:
SURGICAL CENTER, LLC; PREMIER:
ORTHOPAEDIC AND SPORTS MEDICINE:
ASSOCIATES OF SOUTH JERSEY, LLC,:
D/B/A PREMIER ORTHOPAEDIC AND:
SPORTS MEDICINE ASSOCIATES; et al:

AFFIDAVIT OF MERIT

Defendants.

WILLIAM MATUOZZI, M.D., of full age, being duly sworn upon his oath, deposes and says:

- 1. I am a physician currently licensed to practice medicine in the State of New Jersey. My current Curriculum Vitac is attached hereto.
- 2. I have been Board Certified in Diagnostic Radiology for at least five years and have devoted the majority of my time for the year prior to November 20, 2012 in the active clinical practice of diagnostic radiology which continues to the present. My clinical practice involves image guided injections of steroids into patients.

  JAN 9 2015

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3. I have reviewed various documents and medical records regarding the manufacture, sale and distribution of medications including preservative free methylprednisolone acetate (MPA) by New England Compounding Company (NECC) and its use by New Jersey institutions and practitioners including defendant Nitesh Bhagat, M.D.

4. In my opinion, there exists a reasonable probability that the care, skill and knowledge exercised by the defendant Nitesh Bhagat, M.D. in the diagnosis, treatment and/or care of the above named parties fell outside of the acceptable professional standards or practices.

5. I have no financial interest in this litigation.

6. I certify that the foregoing statements made by me are true. I am aware that if any of the statements made by me are wilfully false, I am subject to punishment.

WILLIAM MATOUZZI, M.D.

STATE OF New Jursey
COUNTY OF Union :SS

I CERTIFY that on Dec 17, 2014

william Matouzzi, personally came before me and acknowledged under oath, to my satisfaction, that he:

(a) is named in and personally signed this document; and

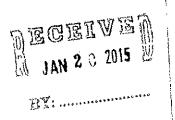
(b) signed, sealed and delivered this document as his act and deed.

JOSEPH 8 PAPERMAN
Notary Public
State of New Jersey
My Commission Expires Jun 27, 2017

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#### NOTICE:

If any defendant contends that this Affidavit of Merit fails to completely satisfy the requirements of the Affidavit of Merit Statute in any way, demand is hereby made that the defendant immediately notify the plaintiff of any such alleged deficiencies so that same may be corrected, if necessary, and within the time constraint of N.J.S.A. 2A:53A-26 et seq.



#### William D. Matuozzi, M.D. 14 Cedar Creek Drive Basking Ridge, New Jersey 07920

#### **EDUCATION**

1

State University of New York, Downstate Medical Center, College of Medicine, Brooklyn, N.Y., M.D., May 1984

Georgetown University Graduate School of Physiology and Biophysics, Washington, D.C.,

M.S. Physiology, May 1980.

State University of New York at Stony Brook, Stony Brook, N.Y. B.S. Biology, June 1979.

#### POSTGRADUATE TRAINING

State University of New York, Health Sciences Center at Brooklyn (formerly SUNY Downstate Medical Center), Brooklyn, N.Y. (M.D., 1984)

Fellowship Equivalent.

CT/Ultrasound/MRI, October 1989-June 1990. Angiography/Interventional Radiology, July 1988-December 1988.

State University of New York Health Sciences Center at Brooklyn, Brooklyn, N.Y. Residency Diagnostic Radiology, June 1986-June 1990.

Montefiore Hospital Medical Center, Bronx, N.Y. Internship and Second Postgraduate Year Internal Medicine, July 1984-June 1986.

#### PRACTICE EXPERIENCE

Overlook Hospital, Summit, N.J., Associate Chairman Atlantic Health System Radiology Residency Program, December 2002 – December 2005.

Overlook Hospital, Summit, N.J. Chairman, Dept. of Radiology, July 1998-January 2003.

Overlook Hospital, Summit, N.J. Vice Chairman, Dept. of Radiology, 2003 - 2012

Overlook Hospital, Summit, N.J. Attending Radiologist, July 1990-Present.

Brookdale Hospital Medical Center, Brooklyn, N.Y., General Radiology, July 1988-June 1990.

The Staten Island Hospital, Staten Island, N.Y., General Radiology, July 1988-June 1990.

#### **AWARDS AND HONORS**

Leo Davidoff Award, 1986.

Outstanding House Officer and Teacher of Medical Students.

Albert Einstein College of Medicine/Montefiore Medical Center, Bronx, N.Y.

#### TEACHING APPOINTMENTS

Chief Resident in Radiology, July 1988-June 1990.

State University of New York Health Sciences Center at Brooklyn, and Kings County Hospital Center, Brooklyn, N.Y.

Clinical Instructor, Radiology, July 1989-June 1990.

Brookdale Hospital Medical Center, Brooklyn, N.Y.

#### **PUBLICATIONS**

\

Idiopathic Cecocolic Intusseception in a 16 year old Boy. Bergman, K., Mones, R., Matuozzi, W. Pediatric Surgery International, Vol. 25, Number 9/September, 2009, 819-821.

#### PROFESSIONAL MEMBERSHIPS

American College of Radiology.

American Institute of Ultrasound in Medicine.

New Jersey Medical Society, Union County Medical Society.

Radiological Society of New Jersey.

#### **CERTIFICATION AND LICENSURE**

American Board of Radiology, Diagnostic Radiology, June 1990.

Diplomate, National Board of Medical Examiners, July 1985.

New Jersey State Licensure, 1990-Present.

New York State Licensure, 1986-Present (Inactive).

# **EXHIBIT B**

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#### BLUMBERG & WOLK, LLC

158 Delaware Street P.O. Box 68 Woodbury, NJ 08096 (856) 848-7472

Counsel for Defendants Premier Orthopaedic and Sports Medicine Associates of Southern New Jersey, LLC, trading as Premier Orthopaedic Associates, Premier Orthopaedic Associates Surgical Center, LLC, Kimberly Yvette Smith, M.D., a/k/a Kimberly Yvette Smith-Martin, M.D., Thomas Dwyer, M.D., Richard C. DiVerniero, M.D., and Richard Strauss, M.D.

## UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

KENNETH CHANN, SR., LAURA CHANN, EMIKO KANESHIKI, JOSEPH LANGLEY, ELDEAN LANGLEY, SAMUEL ELWELL, HELEN ELWELL, EDWARD HIRALDO, and MARILYN HIRALDO (MASONET)

Plaintiffs,

Civil Action No.:

ν.

PREMIER ORTHOPAEDIC
ASSOCIATES SURGICAL CENTER,
LLC et al.

Defendants.

PLAINTIFFS'
CONSENT TO REMOVAL

Plaintiffs, Kenneth Chann, Sr., Laura Chann, Emiko Kaneshiki, Joseph Langley, Eldean Langley, Samuel Elwell, Helen Elwell, Edward Hiraldo, and Marilyn Hiraldo (Masonet) hereby consent to the removal of Civil Action No. ESX-L-7568-14 from the Superior Court of New

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Jersey, Law Division, Essex County, to the United States District Court for the District of New Jersey.

Dated: April 21, 2015

LAW OFFICE OF JEFFREY M.

KEISER-

Jeffrey Keiser, Esq.

76 E. Euclid Ave.

Suite 201

Haddonfield, NJ 08033

Counsel for Plaintiffs Kenneth Chann, Sr., Laura Chann, Emiko Kaneshiki, Joseph Langley, Eldean Langley, Samuel Elwell, Helen Elwell, Edward Hiraldo, and Marilyn Hiraldo (Masonet)

## **EXHIBIT C**

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# UNITED STATES JUDICIAL PANEL on MULTIDISTRICT LITIGATION

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC., PRODUCTS LIABILITY LITIGATION

MDL No. 2419

#### TRANSFER ORDER

Before the Panel: Pursuant to 28 U.S.C. § 1407, plaintiffs in an Eastern District of Michigan action move for centralization of this litigation in the District of Minnesota. This litigation currently consists of four actions pending in two districts, as listed on Schedule A. Since the filing of the motion, the parties have notified the Panel of over 120 related actions pending in various federal districts.<sup>1</sup>

All parties support centralization under Section 1407, but disagree on an appropriate choice for transferee district. Plaintiffs in the four actions on the motion and over 30 potential tag-along actions support centralization in the District of Minnesota. Defendant New England Compounding Pharmacy, the responding co-defendants in over 40 potential tag-along actions, 2 plaintiffs in five potential tag-along actions, and an interested party from the related bankruptcy case 3 request the District of Massachusetts. 4

On the basis of the papers filed and the hearing session held, we find that these actions involve common questions of fact, and that centralization under Section 1407 in the District of Massachusetts will serve the convenience of the parties and witnesses and promote the just and efficient conduct of this litigation. All actions share factual questions relating to injuries arising from the alleged contamination of the injectable steroid methyl-prednisolone acetate at the New England Compounding Pharmacy facility in Framingham, Massachusetts, which allegedly resulted in a multistate outbreak of hundreds of cases of fungal meningitis and other infections. Centralization will

These and any other related actions are potential tag-along actions. See Panel Rules 1.1(h), 7.1 and 7.2. Some of the parties have presented arguments concerning the potential tag-along actions in the current briefing. The parties, however, will have an opportunity to express their views on transfer of potential tag-along actions to MDL No. 2419, as provided for under Panel Rule 7.1.

<sup>&</sup>lt;sup>2</sup> The responding co-defendants are Ameridose LLC, Medical Sales Management, Inc., Barry Cadden, Gregory Conigliaro, Lisa Conigliaro Cadden, Douglas Conigliaro, Carla Conigliaro, and Glenn Chin.

<sup>&</sup>lt;sup>3</sup> The interested party is the Official Committee of Unsecured Creditors.

<sup>&</sup>lt;sup>4</sup> In the alternative, defendant proposes the Eastern District of Michigan.

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-2-

eliminate duplicative discovery; prevent inconsistent pretrial rulings, especially with respect to class certification and discovery issues; and conserve the resources of the parties, their counsel and the judiciary.

We conclude that the District of Massachusetts is an appropriate transferee district. The principal events giving rise to the alleged claims occurred in Massachusetts, the facility at which the contamination allegedly occurred is located there, and the federal and state investigations into New England Compounding Pharmacy are focused there. Thus, the primary witnesses, physical evidence, and documentary evidence likely will be located in Massachusetts. Additionally, defendant is headquartered in Massachusetts, and defendant's bankruptcy case is pending in this district. The Honorable F. Dennis Saylor IV, to whom we assign this litigation, is an experienced transferee judge who is already familiar with the contours of, and has taken preliminary steps to organize, the litigation. We are confident he will steer this litigation on a prudent course.

IT IS THEREFORE ORDERED that pursuant to 28 U.S.C. § 1407, the actions listed on Schedule A and pending outside the District of Massachusetts are transferred to the District of Massachusetts and, with the consent of that court, assigned to the Honorable F. Dennis Saylor IV for coordinated or consolidated pretrial proceedings.

IT IS FURTHER ORDERED that defendant's request to modify the caption of MDL No. 2419 is denied.

PANEL ON MULTIDISTRICT LITIGATION

n G. Heyburn II Chairman

Kathryn H. Vratil Paul J. Barbadoro Charles R. Breyer W. Royal Furgeson, Jr. Marjorie O. Rendell Lewis A. Kaplan

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IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC., PRODUCTS LIABILITY LITIGATION

MDL No. 2419

#### SCHEDULE A

#### Eastern District of Michigan

Brenda Bansale, et al. v. New England Compounding Pharmacy, Inc., C.A. No. 2:12-14559 Lyn Laperriere, et al. v. New England Compounding Pharmacy, Inc., C.A. No. 2:12-14581

#### District of Minnesota

Barbe Puro v. New England Compounding Pharmacy, Inc., C.A. No. 0:12-02605 Rosalinda Edwards v. New England Compounding Pharmacy, Inc., C.A. No. 0:12-02625

# **EXHIBIT D**

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### UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

	<del></del> )
	)
IN RE: NEW ENGLAND	) MDL No. 1:13-md-2419-FDS
COMPOUNDING PHARMACY, INC.	)
PRODUCTS LIABILITY LITIGATION	)
This Document Relates To:	)
	)
All Cases	)
	)
	)

### MEMORANDUM AND ORDER ON TRUSTEE'S MOTION TO TRANSFER CASES AND RELATED MOTIONS

SAYLOR, J.

#### I. Introduction

This litigation involves claims for wrongful death and personal injury arising out of the administration of an injectable steroid, methylprednisolone acetate ("MPA"), manufactured by defendant New England Compounding Pharmacy, Inc. ("NECC"). The complaints allege, in substance, that NECC produced contaminated MPA that led to serious fungal infections and, in some instances, death. As of May 6, 2013, the Centers for Disease Control and Prevention had reported 53 deaths and 733 incidents of fungal infection across 20 states related to injections of contaminated MPA manufactured by NECC since October 2012.

Lawsuits alleging death or injury based on contaminated MPA have been filed in multiple federal and state jurisdictions around the country, including the District of Massachusetts, beginning in November 2012. In February 2013, the Judicial Panel on

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Multidistrict Litigation ("JPML") issued an order under 28 U.S.C. § 1407 transferring various federal-court proceedings to this Court for coordinated and consolidated pretrial proceedings. Subsequent orders of the JPML have transferred other "tag-along" cases to this Court. The matters transferred to this Court typically name additional defendants other than NECC, including certain of its officers and shareholders and certain affiliated corporations.

In the meantime, NECC filed for bankruptcy protection in December 2012. A United States Trustee, Paul Moore, was subsequently appointed to administer the bankruptcy estate.

There are likely to be a large number of victim-claimants in this matter, and it appears undisputed that many of them have suffered death or serious personal injury as a result of the administration of contaminated MPA. It also appears to be undisputed that the pool of available assets to pay claims is likely to be limited; NECC was a fairly small company with relatively few assets, although it appears that there are at least some insurance policies available to cover claims. The trustee, and counsel representing parties in this litigation, essentially agree that it is highly desirable to maximize the resources available to victims and to keep expenditures reasonably low. The trustee, and most counsel, also appear to agree that centralized management of the litigation and claim process is desirable to create the largest possible pool of funds for victims and to distribute those funds fairly, equitably, and with a minimum of expense and delay.

The trustee has moved to transfer *all* personal injury and wrongful death cases, wherever filed, to this Court, in order to facilitate that process and achieve that desirable end. The trustee thus seeks the transfer not only of all federal cases, but of all related state cases, regardless of the identity of the defendants. In substance, the trustee contends that this Court can

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exercise "related-to" jurisdiction over all such matters under 28 U.S.C. §§ 1334 and 157(b), and should transfer the matters to this District.

Consolidation of all NECC litigation in this Court is greatly complicated by the existence of the parallel state-court cases. Some of those cases, particularly those filed after the bankruptcy petition and the automatic stay, name only local healthcare providers (such as pain clinics and individual physicians), and do not name NECC or any affiliates. Some of those plaintiffs object to a centralized proceeding, preferring instead to proceed against those defendants in state court. The trustee, however, contends that those cases could ultimately result in huge claims for contribution or indemnity against the bankruptcy estate, and that such claims could greatly affect or upset the fair administration of the estate, in particular preventing the treatment of all victims fairly and equitably.

Whether, and to what extent, this Court has the power to exercise jurisdiction over state-court litigation, and to transfer it to this District, raises complex and difficult issues of jurisdiction, abstention, and federal-state comity. After careful consideration, and for the reasons set forth below, the trustee's motion to transfer personal injury tort and wrongful death cases will be granted in part and denied in part without prejudice to its renewal. In substance, the Court will assert jurisdiction over, and transfer, all federal cases against NECC and its affiliates, and all state-court cases against NECC and its affiliates, including cases where the claims are third-party claims for contribution or indemnity. The Court will not, however, transfer any state-court cases at this time that do not involve claims against NECC or its affiliates. Any related motions, such as motions to remand or for mandatory abstention, will be treated in a consistent fashion.

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#### II. Background

NECC operated a compounding pharmacy in Framingham, Massachusetts, that combined and mixed ingredients to create specific formulations of pharmaceutical products. NECC was owned and operated by a small group of officers and directors, many of whom were related.

NECC is affiliated with a number of other companies; it is unclear what, if any, role those entities played in the events underlying this litigation.<sup>1</sup>

In fall 2012, health officials traced a number of cases of fungal meningitis to injections in and around the patients' spinal cords (known as intrathecal administration) of MPA that had been manufactured by NECC. In response, NECC initiated a recall of several contaminated batches of MPA. As the scope of the problem became evident, NECC eventually surrendered its pharmacy license and ceased production of all pharmaceutical products.

The first complaint against NECC in this Court alleging personal injury from contaminated MPA was filed on November 2, 2012. The complaint names NECC, two affiliated entities, and various individual officers as defendants. In the ensuing months, similar cases were filed in this District, other federal districts, and in various state courts. Most of those cases name NECC, and affiliated entities or individuals, as defendants. Some, however, name only the healthcare providers who actually distributed or administered the MPA.

On December 21, 2012, NECC filed a petition under chapter 11 of the bankruptcy code.

Among other things, that triggered an automatic stay of proceedings against NECC pursuant to

<sup>&</sup>lt;sup>1</sup> The individuals who have been named in cases before this Court due to their positions within NECC or affiliated entities include Barry J. Cadden, Lisa Conigliaro Cadden, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, and Glenn A. Chin. As of the date of this order, the following entities have been alleged to be affiliated with NECC in cases before this Court: Ameridose, LLC; Medical Sales Management, Inc.; Alaunus Pharmaceutical, LLC; GDC Properties Management, LLC; GDC Holdings, Inc.; and ARL BioPharma, Inc.

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11 U.S.C. § 362(a). Although filed as a chapter 11 petition, there is little, if any, likelihood that the company will resume operations. As noted, the company appears to have relatively limited assets, other than insurance policies. The company also, however, has no significant secured creditors.

On February 12, 2013, the JPML created an MDL proceeding and transferred all actions pending in federal court against NECC to this district for coordinated pretrial proceedings before this Court. The JPML has since transferred multiple "tag-along" actions to this Court.

After the bankruptcy filing, certain plaintiffs filed state-court actions that did not name NECC as a defendant, presumably in order to avoid the operation of the automatic stay.<sup>2</sup> Of particular note are 17 Virginia cases where a Virginia healthcare provider is now the sole defendant. *See, e.g., Wingate v. Insight Health Corp.*, 2013 U.S. Dist. LEXIS 67358 (W.D. Va. May 10, 2013). After the defendant in those actions attempted to have the cases removed to federal court, on May 10, 2013, Judge Wilson of the United States District Court for the Western District of Virginia remanded the cases to state court. *See id.* 

As the schedules attached to the trustee's motion acknowledge, there are now four different categories of cases based on personal injuries resulting from the administration of tainted MPA that are not yet before this Court as part of the MDL: (1) cases pending in other federal courts that have not yet been transferred here; (2) cases pending in state courts where removal is in process; (3) cases pending in state courts that name NECC or affiliated entities as defendants; and (4) cases pending in state courts that do not name NECC or affiliated entities as

<sup>&</sup>lt;sup>2</sup> Other state-court plaintiff's dismissed their claims against NECC after the bankruptcy filing.

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defendants.<sup>3</sup> The trustee's motion asks the Court to assert jurisdiction over cases in all four categories, whether or not the non-NECC-affiliated defendants have made claims for contribution or indemnity from NECC. The Plaintiffs' Steering Committee ("PSC") appointed by the Court in the MDL proceeding agrees as to the first three categories of cases, but requests that the Court abstain from exercising jurisdiction over what it refers to as a "narrow subset" of cases in the fourth category—pending state-court cases that do not name NECC or affiliated entities as defendants—"where the sole articulated basis for 'related to' jurisdiction is a potential—but as yet unasserted—indemnification or contribution claims against NECP." A small number of such state-court plaintiffs have filed oppositions to the trustee's motion, as well as their own motions requesting the Court to abstain from exercising jurisdiction over their cases.<sup>4</sup>

#### III. Analysis

The difficulties presented by the trustee's motion are significant and implicate a wide range of concerns. Unfortunately, no solution can equally address all of these concerns, and each comes with its own troublesome set of questions.

If the Court were to decline to assert jurisdiction over the state-court cases, it might make

<sup>&</sup>lt;sup>3</sup> Which court has jurisdiction over a case in which removal has not yet been perfected is not entirely settled. Pursuant to 28 U.S.C. 1446(d) removal is effected after the defendant takes three procedural steps: (1) filing a notice of removal in federal court, (2) filing notice of removal in state court, and (3) giving prompt written notice to all adverse parties. See 14C CHARLES ALAN WRIGHT & ARTHUR R. MELER, FEDERAL PRACTICE AND PROCEDURE § 3736 (4th ed. 2009). Some courts have held that after notice has been filed with the federal court, but before notice has been filed with the state court, both courts retain concurrent jurisdiction over the case until such notice is filed. Resolution Trust Corp. v. Nernberg, 3 F.3d 62, 69 (3d Cir. 1993) ("The requirement of notice to the state court is an important part of the removal process and has been held necessary to terminate the state court's jurisdiction.") (citing Stephens v. Portal Boat Co., 781 F.2d 481, 482 n.1 (5th Cir. 1986)).

<sup>&</sup>lt;sup>4</sup> See, e.g., Opposition filed by Roanoke Area Lichtenstein Fishwick Intervenors (Virginia); Opposition filed by Tracy Maccoux (Minnesota); Opposition filed by Chance Baker, Patrick Johnston, Ferman Wertz (Virginia); Opposition filed by Roanoke Gentry Locke Plaintiffs (Virginia); Roanoke Gentry Locke Plaintiffs' Motion for Mandatory Abstention.

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it difficult or impossible to resolve the entire litigation in an equitable or efficient manner. Any cases that remain pending in state court could ultimately result in large judgments and corresponding claims for contribution or indemnity against the estate of NECC. Pursuant to the bankruptcy code, such claims would normally have to be considered on equal footing with the claims of injured plaintiffs against the estate as claims of unsecured creditors. Because all unsecured creditors are normally paid pari passu (that is, proportionally and without preference) based on the amount of their claims, even one large contribution or indemnity claim against the estate could greatly diminish, or virtually eliminate, the amount available to be paid to the remaining claimants. See 11 U.S.C. § 1123(a)(4) (any reorganization plan must "provide the same treatment of each claim or interest of a particular class, unless the holder of a particular claim or interest agrees to a less favorable treatment of such particular claim or interest"); In re-Combustion Engineering, Inc., 391 F.3d 190, 239-42 (3d Cir. 2004) (reversing confirmation of a plan of reorganization which provided for disparate treatment of subcategories of personal injury claims); In re Congoleum Corp., 2010 U.S. Dist. LEXIS 72431, 12-13 (D.N.J. July 19, 2010) (affirming bankruptcy court's finding that prejudgment personal injury claimants and breach of contract claimants were similarly situated and therefore must receive similar treatment under a plan of reorganization). In addition, the threat of contingent contribution or indemnity claims becoming fixed after judgment or settlement of the MDL plaintiffs' claims would likely require the plan of reorganization to reserve specific funds. See 11 U.S.C. § 502(e) and (j).

Furthermore, allowing some state-court cases to proceed without consolidation in the MDL creates the possibility of inconsistent rulings or judgments on factual or scientific issues that may greatly complicate the resolution of these matters. And litigation in multiple courts also

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threatens to impose significant discovery burdens, as discovery from many of the same people and entities may be sought on multiple occasions.

If, however, the Court were to assert jurisdiction over all the cases listed by the trustee—including state-court cases where no claims against NECC or its affiliates have yet been asserted—it would have to do so based on a very broad reading of federal subject-matter jurisdiction. As will be discussed, the boundaries of that jurisdiction are very far from clear, and it is therefore uncertain whether the Court even has the authority to act. Even if subject-matter jurisdiction exists, the Court must then consider issues of both mandatory and discretionary abstention. And assuming those hurdles are overcome, in order to effect a transfer of state cases, the Court might be required to enjoin state-court proceedings—a highly disfavored judicial remedy, the use of which is explicitly restricted by the Anti-Injunction Act, 28 U.S.C. § 2283.

Under the circumstances, the Court has concluded that a somewhat cautious approach is appropriate. In substance, the Court will grant the motion to transfer (1) any case pending in federal court against NECC or any affiliated entity or individual, (2) any such case that is in the process of removal to federal court, and (3) any case pending in any state court in which a party has made a claim against NECC or any affiliated entity or individual, including third-party claims for contribution or indemnity. However, as to state-court proceedings not naming NECC or any affiliated entity or individual, the motion will be denied without prejudice to its renewal.

#### A. Cases Against NECC Affiliates Only

The Court must first determine whether it has subject-matter jurisdiction over cases filed by plaintiffs against NECC affiliates but not against NECC. As noted, such cases are pending in

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both federal and state courts.

According to the trustee, NECC has express contractual indemnification obligations to many of the affiliated defendants, including, but not limited to, Barry Cadden, Greg Conigliaro, Lisa Conigliaro, Carla Conigliaro, Glenn Chin, GDC, and MSM. The individual defendants are also additional insureds under at least one of NECC's insurance policies.

The trustee contends that cases against affiliated entities and individuals are subject to the Court's bankruptcy jurisdiction under 28 U.S.C. § 1334. Section 1334 provides district courts with original, but not exclusive, jurisdiction over "all civil proceedings arising under title 11, or arising in or related to cases under title 11." 28 U.S.C. § 1334 (emphasis added). As discussed below, courts have held that related-to jurisdiction exists over cases against non-debtor defendants whom the debtor has an automatic obligation to indemnify or defend. See, e.g., Cambridge Place Inv. Mgmt. v. Morgan Stanley & Co., 2010 U.S. Dist. LEXIS 142954 (D. Mass. 2010); City of Ann Arbor Empls. Ret. Sys. v. Citigroup Mortg. Loan Trust Inc., 572 F. Supp. 2d 314 (E.D.N.Y. 2008); In Re Brentano's, Inc., 27 Bankr. 90 (S.D.N.Y. 1983). The trustee has asserted (and no party has disputed) that NECC owes such an obligation to the affiliated entities and individual defendants. Indeed, no party appears to dispute the Court's power to assert subject-matter jurisdiction over cases naming any NECC-affiliated entity or individual as a defendant.

Accordingly, the Court has subject-matter jurisdiction over any cases pending in federal or state court against entities or individuals affiliated with NECC, whether or not NECC is named as a defendant.

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#### B. <u>Motion to Transfer - Federal Cases</u>

The potential transfer of cases presently pending in other federal courts, and those now pending in state courts where removal is in process, does not appear to present any significant jurisdictional or venue-related issues. Indeed, no party has opposed the transfer of these categories of cases, and the JPML's initial transfer order establishing the MDL specifically contemplates the transfer of such "tag-along" actions pending in various district courts.

Since the date of the initial transfer order, the JPML has transferred to this Court more than 100 "tag-along" cases that had been pending in other federal district courts. The Court has no reason to believe that any federal cases that are the subject of the trustee's transfer motion will not receive similar treatment from the JPML and be transferred to this Court in due course. However, should the situation arise that a case pending in federal court, over which this Court could properly exercise related-to jurisdiction, is not transferred by an order of the JPML, this Court will presumably act to assert jurisdiction over it. Until the Court is made aware of such a situation, it will simply await the JPML's transfer orders for any cases now pending in other federal courts or that are in the process of being removed.

#### C. Motion to Transfer - State Cases

The more difficult set of issues concerns the potential transfer of the state-court cases in which no NECC affiliate is named as a defendant, or in which an NECC affiliate is named only as a third-party defendant in a claim for contribution or indemnity.

#### 1. Subject-Matter Jurisdiction

The Court must first determine whether it has subject-matter jurisdiction over the cases that the trustee seeks to have transferred here. If the Court lacks subject-matter jurisdiction over

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any case, it cannot constitutionally adjudicate that case, regardless of the practical considerations or efficiency benefits.

#### a. 28 U.S.C. § 157(b)(5)

The trustee has cited 28 U.S.C. § 157(b)(5) as the primary basis for the authority to transfer the state-court personal injury and wrongful death actions to this Court. Section 157(b)(5) provides as follows:

The district court shall order that personal injury tort and wrongful death claims shall be tried in the district court in which the bankruptcy case is pending, or in the district court in the district in which the claim arose, as determined by the district court in which the bankruptcy case is pending.

28 U.S.C. § 157(b)(5).

The trustee's reliance on this provision as the basis for subject-matter jurisdiction is misguided. The Supreme Court recently held that "§ 157(b)(5) is not jurisdictional," but rather a venue provision. *See Stern v. Marshall*, 131 S. Ct. 2594, 2606 (2011). In reaching that conclusion, the Supreme Court reasoned as follows:

Section 157(b)(5) does not have the hallmarks of a jurisdictional decree. To begin, the statutory text does not refer to either district court or bankruptcy court 'jurisdiction,' instead addressing only where personal injury tort claims 'shall be tried.'

The statutory context also belies [the] jurisdictional claim. Section 157 allocates the authority to enter final judgment between the bankruptcy court and the district court. See §§ 157(b)(1), (c)(1). That allocation does not implicate questions of subject matter jurisdiction. See § 157(c)(2) (parties may consent to entry of final judgment by bankruptcy judge in non-core case). By the same token, § 157(b)(5) simply specifies where a particular category of cases should be tried.

Id. at 2607.

Accordingly, this provision does not confer any additional jurisdiction on the district courts, and thus the Court must find an alternative basis for the assertion of subject-matter

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jurisdiction if it is to order the transfer of any state-court cases to this Court.5

#### b. <u>28 U.S.C.</u> § 1334

If § 157(b)(5) cannot itself provide the basis for federal jurisdiction over the state-court cases, the Court must look elsewhere for a statutory grant of jurisdiction. As the parties acknowledge, jurisdiction over the vast majority of these cases depends on the Court's interpretation of its bankruptcy jurisdiction under 28 U.S.C. § 1334.

Section 1334 provides district courts with original, but not exclusive, jurisdiction over "all civil proceedings arising under title 11, or arising in or related to cases under title 11." 28 U.S.C. § 1334. The scope of related-to jurisdiction is "quite broad." In re Boston Reg 'I Med. Ctr., 410 F.3d 100, 105 (1st Cir. 2005). "[A] civil proceeding is related to bankruptcy [if] the outcome of that proceeding could conceivably have any effect on the [bankruptcy] estate." In re G.S.F. Corp., 938 F.2d 1467, 1475 (1st Cir. 1991) (internal quotations omitted), overruled on other grounds by Connecticut Nat'l Bank v. Germain, 503 U.S. 249 (1992); Pacor, Inc. v. Higgins, 743 F.2d 984 (3d Cir. 1984), overruled on other grounds by Things Remembered v. Petrarca, 516 U.S. 124 (1995); TD Bank, N.A. v. Sewall, 419 B.R. 103, 105-06 (D. Me. 2009); In re Twinlabs Personal Injury Cases, 2004 WL 435083, 1 (S.D.N.Y. 2004) ("The standard for 'related to' jurisdiction over a suit in the posture of [an action against non-debtor third parties] is "whether its outcome might have any 'conceivable effect' on the bankrupt estate." (quoting

<sup>&</sup>lt;sup>5</sup> To be clear, transfer of the federal cases that are currently before the Court (whether filed here or transferred under the JPML) is squarely addressed by § 157(b)(5). Section 157(b)(5) states that "personal injury tort and wrongful death claims" are to be tried by a federal district court either in the district where the claim arose or the district where the bankruptey case is pending, giving the district court in the district where the bankruptey case is pending discretion to choose between the two venue options. NECC filed for bankruptey in the District of Massachusetts, which gives this Court the discretion under § 157(b)(5) to determine the appropriate venue for personal injury and wrongful death cases pending in the federal courts related to contaminated MPA manufactured and/or sold by NECC or its affiliates.

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Cuyahoga Equip. Corp. v. Publicker Indus. Inc., 980 F.2d 110, 114 (2d Cir.1992))).6

Such jurisdiction is not unlimited, however. There must be some nexus between the "related" proceeding and the bankruptcy case, such that "the outcome of the litigation potentially could have some effect on the bankruptcy estate, such as altering debtor's rights, liabilities, options, or freedom of action, or otherwise have an impact upon the handling and administration of the bankrupt estate." *In re Boston Reg'l*, 410 F.3d at 105 (internal citations and textual alterations omitted); *see Pacor*, 743 F.2d at 994.

As noted, there are two general categories of state-court cases that are the subject of the trustee's motion: those that name NECC or affiliated entities as defendants, and those that do not. It is undisputed that the Court has related-to jurisdiction over cases in the former category. The outcome of such suits against the debtor and its affiliates certainly "could have some effect on the bankruptcy estate." *In re Boston Reg 1*, 410 F.3d at 105 (internal citations and textual alterations omitted).

The more difficult question is whether the Court has related-to jurisdiction over cases currently pending in state court that do *not* name NECC or affiliated entities as defendants, but rather name *only* third-parties (such as physicians or pain clinics), or in which NECC affiliates are named only in third-party claims for contribution or indemnity.

In *Pacor*, the Third Circuit held that related-to jurisdiction did not exist over a suit by an employee against a distributor of asbestos, even though the employee's success in that suit

<sup>&</sup>lt;sup>6</sup> The First Circuit, along with most other circuits, has adopted the standard set forth in *Pacor*, *Inc. v. Higgins*, 743 F.2d 984 (3d Cir. 1984). *See, e.g., In Re Boston Reg'l*, 410 F.3d at 105 (citing *Pacor*); *In re G.S.F. Corp.*, 938 F.2d at 1475 (same); *In re Santa Clara Cnty. Child Care Consortium*, 223 B.R. 40, 45 n.8 (1st Cir. B.A.P. 1998) (collecting cases); *see also Celotex Corp. v. Edwards*, 514 U.S. 300, 308 n.6 ('The First, Fourth, Fifth, Sixth, Eighth, Ninth, Tenth, and Eleventh Circuits have adopted the *Pacor* test with little or no variation.'').

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would likely cause the distributor to seek indemnification from the debtor, an asbestos manufacturer. *Pacor*, 743 F.2d at 986. The court concluded that the action was, at best, a "mere precursor to the potential third party claim for indemnification by [the distributor] against [the manufacturer]." *Id.* at 995. The court contrasted these facts with those in *In re Brentano's, Inc.*, 27 B.R. 90 (Bankr. S.D.N.Y. 1983), where the debtor's landlord sued the guarantor of the debtor's lease. *Pacor*, 743 F.2d at 995. Because the debtor had agreed to indemnify the guarantor, any recovery against the guarantor would result in automatic liability to the estate, creating related-to jurisdiction. *Id.* In contrast, the employee in *Pacor* was not a creditor of the asbestos manufacturer, and "[a]ny judgment obtained would thus have no effect on the arrangement, standing, or priorities of [the asbestos manufacturer's] creditors." *Id.* at 995-96.

Applying *Pacor*, courts have held that related-to jurisdiction exists over suits by tort plaintiffs, who are potential creditors, against non-debtor third-party defendants in only limited circumstances. One such situation is when a judgment against the third party would automatically convert that third party into a creditor due to an existing contribution or indemnity obligation. *See, e.g., Cambridge Place Inv. Mgmt. v. Morgan Stanley & Co.*, 2010 U.S. Dist. LEXIS 142954 (D. Mass. 2010); *City of Ann Arbor Empls. Ret. Sys. v. Citigroup Mortg. Loan Trust Inc.*, 572 F. Supp. 2d 314 (E.D.N.Y. 2008); *In Re Brentano's*, Inc., 27 Bankr. 90 (S.D.N.Y. 1983).<sup>7</sup>

It remains an open question of law, at least in the First Circuit, whether there is related-to

<sup>&</sup>lt;sup>7</sup> Another situation is when recovery under an action by a creditor against a third party could reduce the amount that the creditor can claim from the estate directly. *See, e.g., TD Bank, N.A. v. Sewall*, 419 B.R. 103 (D. Me. 2009); *In re Baptist Foundation of Arizona*, 2000 WL 35575676, at \*1 (D. Ariz. June 30, 2000); *In re Curran*, 157 B.R. 500 (Bankr, D. Mass. 1993). None of the cases that the trustee seeks to have transferred to this Court present that situation.

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jurisdiction over a case against a non-debtor, third-party defendant who has a *potential* (as opposed to an actual) claim for contribution or indemnity against the debtor. *See Cambridge Place*, 2010 U.S. Dist. LEXIS 142954 (noting that "[t]he First Circuit has not yet addressed the appropriate standard to be applied in evaluating whether contractual indemnification obligations give rise to 'related to' bankruptcy jurisdiction."); *see also In re Santa Clara County Care Consortium*, 223 B.R. 40 (B.A.P. 1st Cir. 1998) ("[T]he determination of whether a removed state court proceeding is sufficiently related to a debtor's bankruptcy to confer subject matter jurisdiction is complicated by what appears to be contradictory opinions.").

The Third Circuit, in a line of cases after *Pacor*, has clarified its view that related-to jurisdiction does not exist over a case against a non-debtor defendant if another lawsuit would be necessary before the bankruptcy estate would be impacted. *See, e.g., In re W.R. Grace & Co.*, 591 F.3d 164, 169 (3d Cir. 2009) (finding no related-to jurisdiction where there would first have to be a finding in the state-court action and then a separate suit to pursue a claim for indemnification before there could be any impact on the bankruptcy estate); *In re Combustion Eng'g*, 391 F.3d 190, 231-32 (3d Cir. 2004) ("[A]ny indemnification claims against Combustion Engineering . . . would require the intervention of another lawsuit to affect the bankruptcy estate, and thus cannot provide a basis for 'related to' jurisdiction."); *In re Federal-Mogul Global, Inc.*, 300 F.3d 368, 382 (3d Cir. 2002) ("The test articulated in *Pacor* for whether a lawsuit could 'conceivably' have an effect on the bankruptcy proceeding inquires whether the allegedly related lawsuit would affect the bankruptcy proceeding without the intervention of yet another lawsuit.").

The Fifth Circuit, taking a slightly more expansive view of related-to jurisdiction, has

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emphasized the difference between "tort contribution" principles and "contractual indemnification rights," asserting jurisdiction over a case based on the latter. *Lone Star Fund V (US)*, *LP v. Barclays Bank PLC*, 594 F.3d 383, 387 (5th Cir. Tex. 2010). At least one bankruptcy court in this circuit has adopted a similar requirement for related-to jurisdiction—that the debtor have "an unconditional duty to indemnify" the third-party defendant. *TD Bank, N.A. v. Sewall*, 419 B.R. 103, 106 (D. Me. 2009) (explaining the basis and rationale for this rule).

The Fourth Circuit, in A.H. Robins Co. v. Piccinin, 788 F.2d 994 (4th Cir. 1986), has read *Pacor* to establish a distinction between a potential claim for contribution from a third-party defendant and a contractual duty to indemnify that defendant. *Id.* at 1001 ("The clear implication of the [Pacor] decision is that, if there had been a contract to indemnify, a contrary result would have been in order."). Although the court ultimately remanded for a hearing on the motion to transfer in that case, citing due process concerns, it clearly intimated that related-to jurisdiction over the claims against non-debtor defendants could exist under § 1334. *See id.* at 1016, 999-1001 (affirming the district court's extension of the mandatory stay to suits against non-debtor defendants based in part on the court's interpretation of related-to jurisdiction).

The Sixth Circuit, in *In re Dow Corning Corp.*, 86 F.3d 482 (6th Cir. 1996), took a more pragmatic approach to related-to jurisdiction, asserting jurisdiction over thousands of claims against non-debtor defendants. In doing so, the court distinguished the potential impact on the estate of the large number of cases before it from that of the single allegedly related suit involved in *Pacor*; noting that "[a] single possible claim for indemnification or contribution simply does not represent the same kind of threat to a debtor's reorganization plan as that posed by the

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thousands of potential indemnification claims at issue here." Dow Corning, 86 F.3d at 494.

The court in *In re Twinlabs Personal Injury Cases*, 2004 WL 435083, 1 (S.D.N.Y. 2004), cited that decision, and took a similar approach, in asserting jurisdiction over personal injury cases against non-debtor defendants. The personal-injury cases at issue were all based on products-liability claims surrounding the manufacture and sale of the diet pill ephedra.

Twinlabs, the manufacturer at issue, filed for bankruptcy. In a brief opinion granting the debtor's motion to transfer a state court case against retailers of ephedra, Judge Rakoff noted that "the retailer defendants . . . will undoubtedly seek indemnity from the Debtors following any judgments against them. Accordingly, from many perspectives, the . . . action against the retailers will have more than a 'conceivable effect' on the bankrupt estate of the Debtors." *Id.*<sup>8</sup>

The situation presented here implicates many of the same concerns that motivated the Sixth Circuit's decision to assert jurisdiction over the claims against non-debtor defendants in *Dow Corning*. Although *Dow Corning* did not distinguish between state-court cases against third-party defendants who had already asserted claims against the debtor and cases against those who merely "intend[ed] to file claims for contribution and indemnification," that may be a relevant, indeed important, distinction. *See* 86 F.3d at 494; *In re Santa Clara*, 223 B.R. at 49 (finding "an insufficient nexus to confer 'related to' subject matter jurisdiction on the bankruptcy court, in state court actions involving non-debtor parties, which *may result in contribution/substitution of creditors without a change in the classification of a claim as it relates to the debtor*.") (emphasis added).

In any event, the issue of subject-matter jurisdiction is far from clear, and there appears

The court in Twinlabs did not discuss the jurisdictional issues in any greater depth.

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to be no controlling authority. Unfortunately, the consequences of an incorrect judgment may be very substantial indeed; if the Court does not have subject-matter jurisdiction over a matter, any action it may undertake in that matter will be entirely void. Under the circumstances, the Court will take a two-step approach.

First, the Court concludes that it has related-to subject-matter jurisdiction under § 1334 over any state-court case in which any plaintiff has asserted a claim, or any defendant has asserted a claim for contribution or indemnity, against NECC or any affiliated entity or individual. Such a claim could clearly have an effect, indeed a substantial effect, on the bankruptcy estate.

However, as to state-court cases in which a claim against NECC or an affiliated entity or individual is possible, but has not yet been asserted, the Court will assume the existence of subject-matter jurisdiction, but will abstain from exercising any such jurisdiction. The factors governing the exercise of discretionary abstention, and the reasoning of the Court, are addressed below.

The transfer of some, but not all, state-court cases might be something of a pointless exercise if the possibility remains that a state-court defendant could make a future claim in the bankruptcy case for contribution or indemnity, upsetting the effort to make an equitable distribution to the victims and other creditors. Indeed, that is the essential basis of the trustee's motion: that the Court *must* transfer *all* state-court cases to foreclose that very possibility.

The Court is not convinced, at least at this stage, that such a step is necessary. Other possible courses of action might produce the desired consolidation and finality, without resolving difficult issues of jurisdiction and abstention and without intruding unnecessarily into

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the proceedings of state courts. For example, if the Bankruptcy Court were to set a relatively early bar date for the filing of claims against the estate, it would appear that any defendant in a state-court action would be effectively forced to decide whether it wanted to file a claim for contribution or indemnity against the estate. Such a claim, in turn, would probably permit the exercise of federal jurisdiction over the underlying matter. Any defendant who did not file a claim would be barred, and the state-court case could proceed to judgment without interference from the federal court. Either way, the desired goals would be achieved with a relatively minimal degree of risk or intrusion.

In any event, the Court does not need to reach the issue at this juncture. If the balance of factors shifts over time, the Court can revisit the issue, and if necessary (and appropriate) can issue further orders concerning the exercise of related-to jurisdiction.

#### 2. Abstention

If this Court has subject-matter jurisdiction over cases now pending in state courts, the question arises whether it should abstain from asserting such jurisdiction, either pursuant to the mandatory abstention provisions of § 1334(c)(2), or the discretionary abstention provisions of § 1334(c)(1).9

#### a. Mandatory Abstention Under § 1334(c)(2)

Section 1334(c)(2) requires district courts to abstain from asserting related-to jurisdiction over state-law claims in certain circumstances. The statute provides as follows:

Upon timely motion of a party in a proceeding based upon a State law claim or State law cause of action, related to a case under title 11 but not arising under title 11 or arising in a

<sup>&</sup>lt;sup>9</sup> Certain Virginia state-court plaintiffs have likewise moved to compel the Court to abstain from transferring their specific cases pursuant to § 1334(c)(2).

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case under title 11, with respect to which an action could not have been commenced in a court of the United States absent jurisdiction under this section, the district court shall abstain from hearing such proceeding if an action is commenced, and can be timely adjudicated, in a State forum of appropriate jurisdiction.

28 U.S.C. § 1334(c)(2).10

Section 1334(c)(2) must be read in conjunction with 28 U.S.C. § 157(b)(4), which states that "[n]on-core proceedings under section 157(b)(2)(B) . . . shall not be subject to the mandatory abstention provisions of section 1334(c)(2)." And § 157(b)(2), in turn, provides that "the liquidation or estimation of contingent or unliquidated personal injury tort or wrongful death claims against the estate for purposes of distribution in a case under title 11" are non-core claims. 28 U.S.C. § 157(b)(2)(B) (emphasis added).

A strict textual reading of the statutes may lead to the conclusion that personal injury and wrongful death claims asserted against non-debtor third parties (for example, against various healthcare providers), and not against the bankruptcy estate, are subject to the mandatory abstention provisions of § 1334(c)(2). This is the reading afforded the statutory language by Judge Wilson in *Wingate*. 2013 U.S. Dist. LEXIS 67358.

Other district courts, however, have extended the exception of § 157(b)(4) from mandatory abstention to claims against non-debtor third-parties where indemnification

abstention: (1) a timely motion requesting abstention; (2) an essentially state-law cause of action; (3) a non-core proceeding—one that is only "related to" the bankruptcy case; (4) a lack of federal jurisdiction absent the existence of the bankruptcy case; and (5) an ongoing state-court proceeding that be timely adjudicated. In re Southmark Corp., 163 F.3d 925, 929 n. 2 (5th Cir. 1999). There is some dispute as to whether the state-court proceeding must have already been commenced at the time of the bankruptcy filing for mandatory abstention to apply. Compare In re Container Transport, Inc., 86 B.R. 804, 805 (E.D.Pa.1988) ("Consistent with all known authority and our proclivity to exercise our jurisdiction over matters related to our bankruptcy cases to expedite their disposition, we hold that the presence of a state court action is a necessary condition to invoke 28 U.S.C. § 1334(c)(2).") with Langston Law Firm v. Mississippi, 410 B.R. 150, 155 (S.D.N.Y. 2008) ("The language of § 1334(c)(2)—that an 'action is commenced . . . in a State forum'—does not on its face require the commencement of the state action prior to the bankruptcy action.").

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agreements existed between those third-parties and the debtor. *See Abbatiello v. Monsanto*, 2007 WL 747804, 3 (S.D.N.Y. March 8, 2007) ("the exception to mandatory abstention also applies to litigation against [third-party defendants], because [debtor] is obligated to indemnify [third-party defendants] for any judgment awarded against them."); *Berry v. Pharmacia Corp.*, 316 B.R. 883 (S.D. Miss. 2004) ("[G]iven the nature of the relationship and degree of identity between the debtor [and the third-party defendant], the rationale for exempting personal injury and wrongful death claims against the debtor's estate from the mandatory abstention provision applies fully to the claims against [third-party defendant]. Under the terms of the Distribution Agreement, [third-party defendant] claims a right to absolute indemnity from [debtor] for any judgment that might be rendered against it, so that a judgment against [third-party defendant] is, in practical effect, a judgment against [third-party defendant].").

Judge Wilson acknowledged these cases and their reasoning, but found that no such indemnification agreement existed between NECC and the third-party defendant. He therefore concluded that the mandatory abstention provision of § 1334(c)(2) required that the matter be remanded to state court. *See Wingate*, 2013 U.S. Dist. LEXIS 67358,

The trustee argues that Judge Wilson ignored Congress's motivation for crafting an exception from mandatory abstention for personal injury and wrongful death claims and interpreted the statute too narrowly. That motivation has been aptly summarized as follows:

In short, Congress, recognizing that the unpredictable and substantial verdicts that are often produced in personal injury tort and wrongful death claims could have potentially deleterious effects on a debtor's estate—particularly when, because of the automatic stay provisions of the Bankruptcy Code, a debtor-defendant may not have participated in the underlying trial—concluded that, in non-core proceedings such as the one at bar, the mandatory abstention provision of § 1334(c)(2) should not apply.

Beck v. Victor Equipment Co., Inc., 277 B.R. 179, 180 -181 (S.D.N.Y. 2002) (Rakoff, J.).

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Those same concerns are present here. Even in the absence of contractual indemnity agreements, the third-party defendants in the pending state-court actions may have claims for contribution or common-law indemnity from NECC in the event that they are found liable in state court. Those potential state-court verdicts pose the type of threat Congress had in mind when it crafted the exception to § 1334(c)(2)—they can be "unpredictable and substantial" and even being required to contribute to their satisfaction "could have potentially deleterious effects on a debtor's estate." Beck, 277 B.R. at 180 -181. This is particularly true in circumstances such as this, where the cause of action arises out of an allegedly defective product manufactured by the debtor. In many, if not all, jurisdictions, under ordinary circumstances, the debtor would be strictly liable for the harm caused by the defective product, even if there may have been a thirdparty interposed between the debtor and the tort claimant in the supply chain. See, e.g., Brown v. Superior Court, 751 P.2d 470, 482-483 (Cal. 1988) (finding that, "in accord with almost all our sister states that have considered the issue . . . a manufacturer is not strictly liable for [side effects caused by a prescription drug so long as the drug was properly prepared and accompanied by warnings of its dangerous propensities. . . [However, a manufacturer is] subject to liability for manufacturing defects"); Ayyash v. Henry Ford Health Sys., 210 Mich. App. 142, 147 (Mich. Ct. App. 1995) ("'the essence of the relationship' between the hospital and the patient and the physician and the patient is the provision of a service, not the sale of a product, and, therefore, products liability theories [are] inapplicable. . . . Further, whereas imposing strict liability on manufacturers arguably may promote greater care in manufacturing safer products, imposing strict liability on hospitals and physicians would not.").

The Court must interpret the statutory language in the context of those practicalities. The

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phrase "personal injury tort or wrongful death claims against the estate," as used in § 157(b)(2)(B), can fairly be read to encompass not only personal injury and wrongful death claims, but also claims for contribution or indemnity that derive from personal injury or wrongful death claims. Contribution or indemnity claims are simply procedural vehicles for asserting liability against the estate for some underlying harm. If the underlying harm giving rise to the estate's potential liability involves personal injury or wrongful death, the claim against a third-party concerning that harm is, in substance, a "personal injury tort or wrongful death claim against the estate" and therefore covered by the exception in § 157(b)(2)(B). This reading is more congruent with Congress's motivation in crafting the exception to mandatory abstention.

A narrower reading would create a potentially gaping loophole in the carefully crafted system for the orderly administration of bankruptcy estates. Section 157(b)(2)(B), therefore, provides an exception from mandatory abstention for personal injury and wrongful death claims against non-debtor third-parties for contribution or indemnification.

Accordingly, this Court finds that the mandatory abstention provision of § 1334(c)(2) does not apply to any of the state-court cases at issue.

#### b. <u>Discretionary Abstention Under § 1334(c)(1)</u>

In circumstances where § 1334(c)(2) does not strictly require abstention, § 1334(c)(1) nonetheless gives district courts discretion to abstain from asserting related-to jurisdiction over state-law claims. The statute provides as follows:

Except with respect to a case under chapter 15 of title 11, nothing in this section prevents a district court in the interest of justice, or in the interest of comity with State courts or respect for State law, from abstaining from hearing a particular proceeding arising under title 11 or arising in or related to a case under title 11.

28 U.S.C. § 1334(c)(1).

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Courts have articulated twelve factors that should be considered when deciding whether or not to abstain under § 1334(c)(1). Those factors are as follows:

- (1) the effect or lack thereof on the efficient administration of the estate if a Court recommends abstention;
- (2) the extent to which state law issues predominate over bankruptcy issues;
- (3) the difficulty or unsettled nature of the applicable state law;
- (4) the presence of a related proceeding commenced in state court or other nonbankruptcy court;
- (5) the jurisdictional basis, if any, other than 28 U.S.C. § 1334;
- (6) the degree of relatedness or remoteness of the proceeding to the main bankruptcy case;
- (7) the substance rather than form of an asserted "core" proceeding;
- (8) the feasibility of severing state law claims from core bankruptcy matters to allow judgments to be entered in state court with enforcement left to the bankruptcy court;
- (9) the burden [on] the court's docket;
- (10) the likelihood that the commencement of the proceeding in bankruptcy court involves forum shopping by one of the parties;
- (11) the existence of a right to a jury trial; and
- (12) the presence in the proceeding of nondebtor parties.

In re Twin Laboratories, Inc., 300 B.R. 836, 841 (S.D.N.Y. 2003).

Here, the Court finds that the balance of those factors weighs against discretionary abstention, except as those cases pending in state courts that do not involve any claims against NECC-affiliated entities or individuals.

As noted, the most efficient use of the limited resources of the judicial system, and the fairest and most efficient distribution of the assets of the estate, would be for all of the related cases to be consolidated in one court. Abstention would be counterproductive to that end. In addition, the state-law claims in the cases at issue are primarily based on well-settled principles of tort and product liability; a federal court could likely adjudicate them without being required to decide unresolved issues of state law. This is especially true considering the currently limited scope of the consolidation to pre-trial matters.

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Furthermore, the bankruptcy here is somewhat unusual. The debtor, NECC, had relatively few assets and no secured creditors of any significance. As a result, the primary focus of the plan will likely be satisfying, to the maximum extent possible, the unsecured claims of injured plaintiffs for damages and possibly of third parties for contribution or indemnity. Thus, decisions on factual and legal issues as to liability and damages in all of the state-court cases will likely have tremendous import on the bankruptcy proceedings and the reorganization plan. This is particularly true—indeed, determinative—with respect to cases against third-party defendants who have already asserted their own claims against NECC.

However, a number of factors suggest that abstention is warranted as to some of the cases that the trustee is seeking to have transferred. The issues that will decide the debtor's liabilities and the validity of claims against the estate primarily involve state law. State-court plaintiffs, as well as the states themselves, certainly have a strong interest in having state-law claims adjudicated by the state-court system. Most importantly, the basis for asserting jurisdiction over the state-court cases at issue is confined entirely to § 1334, and that jurisdiction is unclear at best. The potential harm to federal-state comity is potentially at its greatest where the basis for federal jurisdiction is uncertain.

In light of these considerations, the Court will exercise its discretion and abstain from asserting jurisdiction—again, assuming that it exists—over those cases currently pending in state courts involving only state-law claims against defendants other than NECC and its affiliates, and where there is no third-party claim for contribution or indemnity. The Court may, in the future, assert jurisdiction over any such case should the third-party defendant actually assert such a claim, but it will refrain from deciding that issue at this time.

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#### 3. Anti-Injunction Act

The parties acknowledge that the assertion of jurisdiction by this Court over cases pending in state court cases could, under some circumstances, require the issuance of injunctions staying proceedings or otherwise mandating the transfer of state cases. The Anti-Injunction Act provides that a federal court "may not grant an injunction to stay proceedings in a State court except as expressly authorized by Act of Congress, or where necessary in aid of its jurisdiction, or to protect or effectuate its judgments." 28 U.S.C. § 2283.

The trustee contends that enjoining the state-court proceedings against third-party non-debtor defendants would not run afoul of the Anti-Injunction Act because the granting of such an injunction would be "necessary in aid of [the Court's] jurisdiction." § 2283. The Supreme Court has interpreted this exception to the rule as follows:

[w]hile this language is admittedly broad, we conclude that it implies something similar to the concept of injunctions to "protect or effectuate" judgments. Both exceptions to the general prohibition of § 2283 imply that some federal injunctive relief may be necessary to prevent a state court from so interfering with a federal court's consideration or disposition of a case as to seriously impair the federal court's flexibility and authority to decide that case.

Atlantic C. L. R. Co. v. Brotherhood of Locomotive Engineers, 398 U.S. 281, 295 (1970).

The trustee also points to the All Writs Act, 28 U.S.C. § 1651, as well as a few MDL cases from other circuits where injunctions in aid of jurisdiction were upheld. See, e.g., Newby v. Enron Corp., 302 F.3d 295, 300 (5th Cir. 2002).

It may well be the case that this Court could be forced to issue injunctive relief in aid of its related-to jurisdiction in order to effectuate the necessary transfers. But even assuming that the Court has the power to issue an injunction in aid of jurisdiction, it is not immediately apparent such an action is necessary or appropriate at this stage. Such an injunction is something

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of a weapon of last resort, and the Court will not lightly undertake to employ it, particularly when other alternatives may be available. For example, in *Twinlabs*, Judge Rakoff simply directed "[c]ounsel for the Debtors . . . to distribute copies of [his order granting the motion to transfer] to all affected counsel within two business days hereof and to work with them to arrange the expeditious transfer of the *Acuff* case to this Court." *In re Twinlabs*, 2004 WL 435083 at 2. Rather than reach a final decision as to the issue at this stage, the Court will in the first instance work with counsel and ascertain if less drastic measures will achieve the desired goal.

#### 4. Conclusion

For the foregoing reasons, the Court will grant the trustee's motion to transfer as to (1) those cases against NECC or any affiliated entity or individual pending in federal courts, (2) those cases against NECC or any affiliated entity or individual in the process of being removed from state court, and (3) those cases pending in state courts in which any party has asserted a claim (including a claim for contribution or indemnity) against NECC or any affiliated entity or individual. The Court will deny the trustee's motion as to those cases pending in state courts in which a claim against NECC or an affiliated entity or individual is possible, but has not yet been asserted, without prejudice to its renewal. The precise mechanics of effectuating the transfer of cases pursuant to this memorandum and order, including the form of any further order that may be required, will be determined at a later time.

<sup>&</sup>lt;sup>11</sup> The Court assumes, without deciding, that a claim for contribution or indemnity filed in the bankruptcy action would render the underlying state-court action subject to this Court's jurisdiction.

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#### B. Motions to Withdraw Reference

Defendants Ameridose and GDC have filed motions to withdraw the reference of certain personal injury and wrongful death cases from the Bankruptcy Court to this Court. All parties before this Court, except the plaintiffs in those specific actions, support the motions to withdraw.

The relevant statute, 28 U.S.C. § 157(d), provides that "[t]he district court may withdraw, in whole or in part, any case or proceeding referred under this section . . . on timely motion of any party, for cause shown." *See United States v. Kaplan*, 146 Bankr. Rptr. 500, 503 (D. Mass. 1992) (motion is timely if made as promptly as possible in light of the developments in the bankruptcy proceeding or at the first reasonable opportunity).

Consolidation before this Court offers the same practical benefits for these few isolated cases pending before the Bankruptcy Court as it does for all of the other cases that were the subject of the trustee's motion to transfer. However, simply withdrawing the reference to the Bankruptcy Court presents none of the complicated jurisdictional questions discussed at length above. Instead, this Court undoubtedly has related-to jurisdiction over these matters and the discretion to withdraw the reference from the Bankruptcy Court upon a showing of good cause. This Court finds that the benefits of consolidation with the hundreds of other personal injury and wrongful death cases currently before it constitutes the requisite good cause for withdrawal.

Accordingly, the Court will withdraw the reference of all adversary proceedings against NECC and affiliated entities involving personal injury and wrongful death claims from the Bankruptcy Court.

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#### C. Motions to Remand in New Jersey Cases

Plaintiffs in certain New Jersey actions that have been consolidated before this Court pursuant to the JPML's transfer order have recently moved for their specific cases to be remanded to New Jersey state courts.

As an initial matter, the Court finds that it has related-to jurisdiction over these cases by nature of the fact that they all name NECC and/or at least one NECC-affiliated entity as a defendant. For the reasons outlined above, the Court finds that "the outcome of th[ese] proceeding[s] could conceivably have [an] effect on the [bankruptcy] estate. In re G.S.F. Corp., 938 F.2d 1467, 1475 (1st Cir. 1991). Accordingly, the Court will deny the motion to remand the New Jersey cases.

In the alternative, some parties have proposed that the state-law claims against non-NECC-affiliated third-party defendants be severed and remanded. At oral argument, Ameridose endorsed this solution only as an alternative to simply denying the motions to remand outright. In the original motions to remand, the New Jersey plaintiffs opposed severance. However, some plaintiffs, likely realizing the futility of the motions to remand in light of NECC's bankruptcy, have very recently taken the position that severance is appropriate.

With regard to the issue of severance, Fed. R. Civ. P. 21 indeed gives the Court power to "sever any claim against a party." However, in light of the conflicted positions taken by the various New Jersey plaintiffs, and the benefits of consolidation, at least for pre-trial purposes, discussed above, the Court does not find a compelling reason to exercise its discretion and sever

Most of these motions to remand were filed prior to NECC's bankruptcy, and consequently much of the argument against federal jurisdiction was based on the lack of complete diversity between the parties. However, related-to jurisdiction now provides an alternative basis for subject-matter jurisdiction. Indeed, it does not appear from the briefing on these motions that any plaintiff has challenged the Court's § 1334 jurisdiction.

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the claims against third-party defendants in the New Jersey actions. Accordingly, to the extent that the motions to remand seek severance as an alternative, they will also be denied.

#### D. <u>Motions to Remand Massachusetts Cases</u>

Plaintiffs in three Massachusetts actions have moved for their cases to be remanded to Massachusetts state courts. They filed these motions prior to the bankruptcy of NECC and the consolidation of cases before this Court in the MDL. Accordingly, for substantially the same reasons noted above with respect to the New Jersey cases, the Court will deny the motions to remand.

#### E. Motions to Remand Virginia Cases

Plaintiffs in two Virginia actions have moved for their cases to be remanded to Virginia state courts. <sup>13</sup> They filed these motions prior to the consolidation of cases before this Court in the MDL. Accordingly, for substantially the same reasons articulated above with respect to the New Jersey and Massachusetts cases, the Court will deny the motions to remand.

#### F. Motion for Mandatory Abstention in Virginia Cases

Plaintiffs in certain other Virginia actions that were the subject of Judge Wilson's decision in *Wingate*, 2013 U.S. Dist. LEXIS 67358, filed a motion for mandatory abstention pursuant to § 1334(c)(2). For the reasons set forth above, the Court finds that the mandatory abstention provision of § 1334(c)(2) does not apply to these cases, and therefore will deny the motion. However, to the extent that these cases do not yet involve claims against NECC or

<sup>&</sup>lt;sup>13</sup> The eases originating in Virginia that have been removed to this court in which the plaintiffs have filed motions to remand are *Radford v. New England Compounding Pharmacy, Inc., et al.*, 1:13-ev-10688-FDS, and *Rhodes v. New England Compounding Pharmacy, Inc.*, 1:13-ev-10504-FDS.

<sup>&</sup>lt;sup>14</sup> This motion was filed in *Erkan v. New England Compounding Pharmacy, Inc. et al.*, 1:12-ev-12052-FDS and is referred to by the parties and herein as "Roanoke Gentry Locke Plaintiffs' Motion for Mandatory Abstention."

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affiliated entities or individuals, the Court will exercise its discretion to abstain from asserting jurisdiction over them consistent with this memorandum and order.

#### III. Conclusion

For the foregoing reasons:

- (1) The Trustee's Motion to Transfer Personal Injury Tort and Wrongful Death Cases is GRANTED as to (1) those cases against NECC or any affiliated entity or individual pending in federal courts, (2) those cases against NECC or any affiliated entity or individual in the process of being removed from state court, and (3) those cases pending in state courts in which any party has asserted a claim (including a claim for contribution or indemnity) against NECC or any affiliated entity or individual. A list of the pending cases to which this transfer order applies will be entered separately on the docket. The motion is DENIED as to those cases pending in state courts in which no claim against NECC or an affiliated entity or individual has been asserted, without prejudice to its renewal with as to those cases;
  - (2) Roanoke Gentry Locke Plaintiffs' Motion for Mandatory Abstention is DENIED;
  - (3) Defendants' Motions to Withdraw the Reference in the following cases are GRANTED:

Shaffer et al v. Cadden, 1:13-cv-10226-FDS

Schroder et al v. New England Compounding Pharmacy, Inc., 1:13-cv-10227-FDS

Cary v. New England Compounding Pharmacy, Inc., 1:13-cv-10228-FDS

Adams v. Cadden, 1:13-cv-10229-FDS

(4) Plaintiffs' Motions to Remand in the following cases are DENIED:

Thompson v. New England Compounding Pharmacy, Inc.,

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#### 1:12-cv-12074-FDS

- Armstrong v. New England Compounding Pharmacy, Inc., 1:12-cv-12077-FDS
- Guzman v. New England Compounding Pharmacy, Inc., 1:12-ev-12208-FDS
- Devilli, et al. v. Ameridose, LLC, et al., 1:13-cv-11167-FDS
- Marko v. New England Compounding Pharmacy, Inc., et al., 1:13-cv-10404-FDS
- Pennington v. New England Compounding Pharmacy, Inc., et al., 1:13-cv-10406-FDS
- Hannah v. New England Compounding Pharmacy, Inc., et al., 1:13-cv-10407-FDS
- Leaverton v. New England Compounding Pharmacy, Inc., et al., 1:13-cv-10408-FDS
- Jones v. New England Compounding Pharmacy, Inc., et al., 1:13-cv-10409-FDS
- Ramos v. New England Compounding Pharmacy, Inc., et al., 1:13-cv-10410-FDS
- Rios v. New England Compounding Pharmacy, Inc., et al., 1:13-cv-10411-FDS
- Rivera v. New England Compounding Pharmacy, Inc., et al., 1:13-cv-10412-FDS
- Tolotti v. New England Compounding Pharmacy, Inc., et al., 1:13-cv-10413-FDS
- Tayvinsky v. New England Compounding Pharmacy, Inc., et al., 1:13-cv-10414-FDS
- Zavacki v. New England Compounding Pharmacy, Inc., et al., 1:13-cv-10441-FDS
- Letizia v. New England Compounding Pharmacy, Inc.,

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1:13-cv-10442-FDS

Gould v. New England Compounding Pharmacy, Inc., 1:13-cv-10444-FDS

Tisa v. New England Compounding Pharmacy, Inc., et al., 1:13-cv-10446-FDS

Normand v. New England Compounding Pharmacy, Inc., et al., 1:13-cv-10447-FDS

Radford v. New England Compounding Pharmacy, Inc., et al., 1:13-cv-10688-FDS

Rhodes v. New England Compounding Pharmacy, Inc., 1:13-cv-10504-FDS

(5) The Court will issue separate orders in the dockets of the specific cases just referenced as to the motions affected by this order.

So Ordered.

/s/ F. Dennis Saylor
F. Dennis Saylor IV
United States District Judge

Dated: May 31, 2013

## UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

Chambers of
Michael A. Hammer
United States Magistrate Judge

Martin Luther King Federal Building & U.S. Courthouse 50 Walnut Street, Room 2042 Newark, NJ 07101 (973) 776-7858

October 2, 2015

To: All counsel of record

#### LETTER ORDER PURSUANT TO RULE 16.1

RE: Kenneth Chann, Sr. v. Premier Orthopaedic Associates Surgical, LLC Civil Action No. 15-3690 (ES)(MAH)

Dear Counsel:

An in-person initial scheduling conference shall be conducted before the Undersigned at 11:00 a.m. on October 26, 2015.

Counsel are advised that the early disclosure requirements of <u>Fed. R. Civ. P.</u> 26 will be enforced. Therefore, counsel shall immediately exchange the following information without a formal discovery request:

- identities of individuals likely to have knowledge of discoverable facts;
- documents and things in the possession of counsel or the party:
- identities of experts and their opinions;
- insurance agreements in force; and
- statement of the basis for any damages claimed.

At least fourteen (14) days prior to the conference scheduled herein, counsel shall personally meet and confer pursuant to <u>Fed. R. Civ. P.</u> 26(f), and **shall submit a discovery plan to the Undersigned not later than 72 hours prior to the conference with the Court.** The discovery plan shall include (1) a brief summary of the claims and defenses; and (2) a proposed schedule for completing fact and expert discovery. The discovery plan may include a summary of the status of settlement negotiations. (THE DISCOVERY PLAN SHALL BE IN THE FORM ATTACHED AND SHALL BE SUBMITTED JOINTLY.)

At the conference, the Court will address scheduling of all motions. No motions, other than a motion under Fed. R. Civ. P. 12, shall be filed without prior leave of Court. If any motions have already been filed, please advise the Court immediately, in writing, regarding the nature of the motion and its present status. You may submit unopposed applications for <u>pro hac vice</u> admission with my Chambers. Please obtain consent of your adversary prior to filing your application, advising both in your cover letter and proposed Order that you have consent. In addition, the party shall follow the requirements of L.Civ.R. 101.1(c) and submit a certification that states local counsel: (1) is a member of the New Jersey bar in good standing and lists all bars in which counsel is admitted and their contact information, (2) will be responsible for the conduct of the pro hac vice counsel, (3) will sign all pleadings and submissions and make all court appearances, and (4) will ensure that pro hac vice counsel will comply with L.Civ.R. 101.1(c). The certification shall also state whether or not the applicant has received the consent of opposing counsel. The certification of proposed pro hac vice counsel shall include said counsel's actual signature and state that counsel: (1) is a member of a bar in good standing and list all bars in which counsel is admitted and their contact information, (2) will submit to this Court's jurisdiction for discipline, (3) will pay the Clerk's fee, (4) will make payment to the client fund; and (5) will abide by Local Civil Rule 101.1(c).

At the conference, all parties who are not appearing <u>pro se</u> must be represented by counsel who shall have full authority to bind their clients in all pre-trial matters. <u>Counsel shall also be prepared to discuss the merits of the case and have settlement authority</u>. Clients or persons with authority over the matter shall be available by telephone. See <u>L.Civ.R.</u> 16.1(a).

Counsel for plaintiff(s) shall notify any party, who hereafter enters an appearance, of the above conference, and forward to that party a copy of this Order.

The parties must advise this Court immediately if this action has been settled or terminated so that the above conference may be canceled.

Failure to comply with the terms herein may result in the imposition of sanctions.

SO ORDERED this 2<sup>nd</sup> day of October, 2015.

s/ Michael A. Hammer
Hon. Michael A. Hammer
United States Magistrate Judge

Orig: Clerk

cc: Counsel of Record

File

## UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

:

Civil Action No.

	: Plaintiff(s), : Hon.	
	v. : JOINT DISCOVERY PLAN	
	: : Defendant(s). :	
1.	Set forth a factual description of the case. Include the causes of action and affirmative defenses asserted.	
2.	Have settlement discussions taken place? Yes No	
	If so, when?	
	(a) What was plaintiff's last demand?	
	(1) Monctary demand: \$(2) Non-monetary demand:	
	(b) What was defendant's last offer?	
	(1) Monetary offer: \$(2) Non-monetary offer:	
3.	e parties [havehave not] exchanged the information required by <u>Fed.</u> <u>Civ. P.</u> 26(a)(1). If not, state the reason therefor.	
4.	Describe any discovery conducted other than the above disclosures.	
5.	Generally, dispositive Motions cannot be filed until the completion of discovery.  Describe any Motions any party may seek to make prior to the completion of discovery.  Include any jurisdictional Motions and Motions to Amend.	
6.	The parties proposed the following:	
	(a) Discovery is needed on the following subjects:	
	(b) Should discovery be conducted in phases? If so, explain.	
	(c) Number of Interrogatories by each party to each other party:	
	(d) Number of Depositions to be taken by each party:	

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	(e)	Plaintiff's expert report due on	
	(f)	Defendant's expert report due on	
	(g)	Motions to Amend or to Add Parties to be filed by	
	(h)	Dispositive motions to be served withindays of completion of discovery.	
	(i)	Factual discovery to be completed by	
	(j)	Expert discovery to be completed by	
	(k)	Set forth any special discovery mechanism or procedure requested, including data preservation orders or protective orders:	
	(l)	A pretrial conference may take place on	
	(m)	Trial by jury or non-jury Trial?	
	(n)	Trial date:	
7.	Do yo	ou anticipate any discovery problem(s)? Yes No If so, explain.	
8.	proble	o you anticipate any special discovery needs (i.e., videotape/telephone depositions, roblems with out-of state witnesses or documents, etc.)? Yes No f so, explain.	
9.	State whether this case is appropriate for voluntary arbitration (pursuant to <u>L. Civ. R.</u> 201.1 or otherwise), mediation (pursuant to <u>L. Civ. R.</u> 301.1 or otherwise), appointment of a special master or other special procedure. If not, explain why and state whether any such procedure may be appropriate at a later time (i.e., after exchange of pretrial disclosures, after completion of depositions, after disposition of dispositive motions, etc.).		
10.	Is this case appropriate for bifurcation? Yes No		
11.	We [d Judge	o do not] consent to the trial being conducted by a Magistrate	
		Attorney(s) for Plaintiff(s)	
		Attorney(s) for Defendant(s)	

#### United States District Court for the District of New Jersey



#### NOTICE November 2004

Dear Bar Member:

The United States District Court for the District of New Jersey implemented electronic case filing on January 5, 2004. The Case Management/Electronic Case Filing (CM/ECF) system is browser-based and accessible over the Internet. We are excited about the benefits this technology offers to the court and the bar, especially being able to file and view documents 24 hours a day from the convenience of your office or home.

Training is essential to utilize the full capabilities of this system. Attorneys are encouraged to participate in training and register to become e-filers. For your convenience, we are providing three methods of ECF training. Hands-on training classes are offered at each of our three courthouses. You can register for these classes on our web site at **pacer.njd.uscourts.gov**. There is a self-paced ECF tutorial that is accessible from our web site as well. We also offer on-site training that can be arranged at your firm depending on the number of attendees and the availability of suitable facilities by calling (973)-645-4439.

ECF registration forms can be obtained from any of our three offices or completed electronically on our website. It is strongly suggested that you familiarize yourself with the Policies and Procedures that govern the use of this System. The Electronic Case Filing Policies and Procedures are available on our web site, along with our ECF User's Guide and other useful information.

In addition to ECF access, it is recommended that a PACER (Public Access to Electronic Records) account is obtained. A PACER account will provide Filing Users with querying capabilities. PACER is a fee-for-use service offered by the Administrative Office of the United States Courts. Contact the PACER Service Center at (800)676-6856 or on-line at <a href="http://pacer.psc.uscourts.gov">http://pacer.psc.uscourts.gov</a>.

Please be advised that documents not filed electronically but filed in the traditional manner on paper must be accompanied by a floppy diskette or a CD containing the document(s) in PDF format. Each PDF document must not exceed 2MB or 2048KB. If the paper document contains an original signature, then the electronic version contained on the diskette or CD must include a signature line with "s/" (e.g., s/Jennifer Doe).

The real success of this system is a function of the number of lawyers who become registered e-filing users. Upon receipt of your ECF login and password, the court expects you to file electronically. Please take advantage of the CM/ECF training opportunities and become a registered e-filer before e-filing becomes mandatory. Beginning <u>January 31, 2005</u>, electronic case filing will be mandatory for all civil and criminal cases other than pro se cases.

Sincerely,

William T. Walsh Clerk Case 2:15-cy-03690-ES-MAH Document 2 Filed 10/02/15 Page 6 of 6 PageID: 286

# ALTERNATIVE DISPUTE RESOLUTION IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

Mediation is the Alternative Dispute Resolution ("ADR") program in this Court. Mediation is governed by Local Civil Rule 301.1. The mediation program under this rule is supervised by a judicial officer who is available to answer any questions about the program.

Any district judge or magistrate judge may refer a civil action to mediation. This may be done without the consent of the parties. However, the Court encourages parties to confer among themselves and consent to mediation. Moreover, you are reminded that, when counsel confer pursuant to Rule 26(f) of the Federal Rules of Civil Procedure and Local Civil Rule 26.1, one of the topics that <u>must</u> be addressed is the eligibility of a civil action for participation in ADR.

A civil action may be referred to mediation at any time. However, one of the advantages of mediation is that, if successful, it enables parties to avoid the time and expense of discovery and trial. Accordingly, the Court encourages parties to consent to mediation prior to or at the time that automatic disclosures are made pursuant to Rule 26(a)(1) of the Federal Rules of Civil Procedure.

If parties consent to mediation, they may choose a mediator either from the list of certified mediators maintained by the Court or by the selection of a private mediator. If a civil action is referred to mediation without consent of the parties, the judicial officer responsible for supervision of the program will select the mediator.

Mediation is non-judgmental. The role of the mediator is to assist the parties in reaching a resolution of their dispute. The parties may confer with the mediator on an <u>ex parte</u> basis. Anything said to the mediator will be deemed to be confidential and will not be revealed to another party or to others without the party's consent. The first six hours of a mediator's time is free. The mediator's hourly rate thereafter is \$150.00, which is borne equally by the parties.

If you would like further information with regard to the mediation program please review the Guidelines for Mediation, which are available on the Court's Web Site "pacer.njd.uscourts.gov" and appear as Appendix Q to the Local Civil Rules. You may also make inquiries of the judicial officer responsible for supervision of the program.

Civil actions in which there are pro se parties (incarcerated or not) are not eligible for mediation.

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October 6, 2015

#### VIA E-FILING ONLY

The Honorable Esther Salas
United States District Court - District of New Jersey
Martin Luther King Building & U.S. Courthouse
50 Walnut St.
Newark, NJ 07101

RE: Chann et al. v. Premier Orthopaedic Associates et al.

Docket No. 15-cv-3690

#### Dear Judge Salas:

I am writing on behalf of the defendants, Premier Orthopedic and Sports Medicine Associates of Southern New Jersey, LLC, Premier Orthopedic Associates Surgical Center, LLC, and Kimberly Yvette Smith, M.D. to inform you that, due to common questions of fact between this case and others previously consolidated into the multi-district litigation *In Re New England Compounding*, Docket No. 1:13-md-02419-RWZ, I am filing a Notice of Potential Tag-Along in the District of Massachusetts to initiate transfer of this case to that jurisdiction where the MDL is currently pending.

Thank you.

Respectfully,

**BLUMBERG & WOLK, LLC** 

/s/ Christopher M. Wolk

Christopher M. Wolk, Esq.

CMW/dm

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#### **CERTIFICATE OF SERVICE**

I, Christopher M. Wolk, Esq., hereby certify that I caused a copy of the foregoing letter to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: October 6, 2015

/s/ Christopher M. Wolk, Esq. Christopher M. Wolk, Esq.

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Law Offices

### JEFFREY M. KEISER, ESQUIRE

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October 20, 2015

#### PLEASE NOTE CHANGE OF ADDRESS

Honorable Michael A. Hammer, U.S.M.J. United States District Court District of New Jersey Martin Luther King Federal Building 50 Walnut Street, Room 2042 Newark, NJ 07101

Re:

Kenneth Chann Sr., et al v. Premier Orthopedics

Civil Action No. 15-3690 (ES)(MAH)

Dear Judge Hammer:

This letter is a follow-up to the Court's Letter Order pursuant to <u>FRCP</u>16.1 scheduling the case for an inperson conference on October 26, 2015. This confirms my conversation with Your Honor's Law Clerk, Clarissa Gomez. She has directed I write a confirming letter.

The Chann cases are part of a multi-district litigation, In re New England Compounding Pharmacy, Inc., products liability litigation, United States District Court, District of Massachusetts, MDL No. 13-02419-RWZ, which cases are being managed by Judge Rya Zobel in the District Court. As recently as October 7, 2015, she has entered an order retaining jurisdiction of all of the cases within the class for discovery and trial.

There is currently an order entered by Judge Zobel setting forth a discovery plan that incorporates these cases. We, unfortunately, experienced some logistical difficulty in getting these cases removed from the State Court and consolidated into the MDL. I am advised that Mr. Wolk will be submitting the necessary pleadings to get these cases consolidated with the MDL in Massachusetts in short order with our consent.

Because of the status of these cases, it would appear that a conference under <u>FRCP</u>16 would be a waste of the Court's time. We are prepared to do whatever is necessary to expedite the transfer of the cases to the MDL docket.

Thank you for your consideration in this matter.

Respectfully yours,

JEFFKEY M. KEISER

JMK/ci

cc: Christopher Wolk, Esquire Mark Zamora, Esquire